

QUALITY AND OUTCOMES IN ORAL AND MAXILLOFACIAL SURGERY



Inaugural Report 2021/22



DATA COLLECTION PERIOD 2021-2022



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Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS): The Inaugural Report 2021/2

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Foreword by Ian Martin

I was privileged to have held the offices of both Chairman of Council and President of BAOMS. During my tenure as chairman, I also held the Presidency of the Federation of Surgical Specialty Associations (FSSA). Following a number of high-profile surgical service failures, there was increasing political pressure for commissioners to carefully consider whether certain surgical procedures were of “low clinical value or effectiveness” and also for the outcome of individual surgeons’ procedures to be made public. Amongst the 10 principal surgical specialties, it was clear that oral & maxillofacial surgery was considerably behind many of the other specialties in its ability to demonstrate the ultimate value of certain procedures, and also to identify unwarranted variations in practice thereby permitting individual surgeons and teams to identify potentially remediable factors in their service provision and reduce unwarranted adverse outcomes. The Department of Health (DoH) and NHS were keen to name and shame individual surgeons, and indeed did so, by citing crude mortality data for a number of named surgeons, with the inevitable consequence of sensational media reporting. What however was missing was good reliable and relevant data relating to outcomes. Whilst the use of mortality data in specialties like cardiac surgery, where individual surgeons undertake a high volume of a small range of procedures with an expected

and statistically measurable binary outcome (e.g., death), in a specialty like OMFS where individual surgeons perform a wide range of procedures, but often in relatively small numbers and with exceedingly low mortality, the process was clearly inappropriate, and was condemned by the FSSA. The DoH and NHS had indicated that it would support and resource much better automated data collection in order to support meaningful analysis of surgical outcomes, however this never materialised. Meanwhile the threat of withdrawing funding for procedures where there was insufficient data to prove their clinical benefit was growing amidst austerity measures being applied to the NHS. It was within this wider political context therefore that I chose to use my BAOMS Presidential Initiative Fund to kick start a meaningful and relevant data collection system, to ensure that as surgeons we could have the evidence to demonstrate the value that our procedures provide for patients, and to permit individual surgeons and teams to benchmark themselves and ensure their performance was as good as possible. I am delighted to see in this first report, that this process is now at the embryonic stages of enabling those ambitions for our specialty, and I look forward to seeing the programme continue to mature in the coming years.

Ian C Martin

Past President, British Association of Oral and Maxillofacial Surgeons



Foreword by Cyrus Kerawala

The QOMS initiative at last brings Oral and Maxillofacial Surgery into line with many other specialties in allowing us to repay the trust shown in us by our patients by finally fulfilling the professional, moral and social responsibility of knowing what we are doing and how well we are doing it. The aspiration to improve our skills and practice can only be enhanced by data which ultimately forms the baseline for quality improvement on a personal and organisational level.

This first QOMS report is the culmination of the vision, focus and tenacity of many over the course of the last four years. In an era of evidence-based practice and public scrutiny this collective endeavour provides us with an invaluable resource which will not only be of utility in day-to-day practice but also permits the benchmarking and evolution of all our surgical practices in concert with the aims of GIRFT and NCIP. The fact that the data has been

collected by the specialty itself provides us with a degree of reassurance that is sometimes missing in information collated by external agencies.

This report is an important milestone and is all the more remarkable given that this major undertaking has been completed in the challenging times of the COVID-19 pandemic and its immediate aftermath. There is no doubt that in future years data richness will improve and as it does so both quantity and quality will be enhanced. All involved, be they members of the wider Oral and Maxillofacial Surgery team, data co-ordinators, QOMS committee members or report authors themselves, are to be commended for their remarkable efforts and mutual resilience in bringing to fruition what many thought would never be possible.

Professor Cyrus Kerawala

61st President, British Association of Oral and Maxillofacial Surgeons



Foreword by Marisa Mason

Quality improvement (QI) programmes, led by healthcare professionals, are now commonplace. In fact, if you don't have one you are the odd one out. I am not being flippant; specialty-owned QI programmes are essential, they provide a sort of kite mark of good practice and continued professional development at a time when patients are increasingly aware that they can ask questions of those treating them. While 'big data' collected by external organisations such as GIRFT or NCIP/HES can provide some degree of oversight into what is happening within a specialty, it cannot provide the degree of fine detail that only those working in the field can. Furthermore, there are no datasets that encompass all four nations; national, specialty led programmes are essential to achieve a cohesive dataset that can add value and complement the datasets currently collected.

It is not easy setting up such a specialty led programme, and not everyone in a specialty will have the foresight to be an early adopter; some will need to be carried along until convinced, and of more concern is that some, hopefully a minority, may never think it is a good idea. But there is a high level of professional maturity to being able to open yourself or your department up to scrutiny for the benefit of others. Certainly, I am always wary of a clinician who will happily spend an hour on the phone explaining why they are too busy to take part in one of our NCEPOD studies and will not spend an hour reflecting on the care they had provided. One comment always jumps to mind "I haven't got time to look back at those who have died, I need to focus on the living." I understood what they meant, there was no disrespect intended to the patients involved, but the day job was busy and pressured, and protected time for taking part in

additional work, reflecting on past care, is often not made available in job plans. But if we don't take time to learn from how things were done in the past how can we improve?

QOMS has evolved at a steady pace. I have been impressed with the determination to get it up and running, even in the lowest moments, such as waiting on information governance approvals that took an eternity, and of course the added delay injected by the pandemic. However, its current success is down to a relatively small group of committed individuals and units who are steering it. I cannot deny that I have been struck, on occasion, by the lack of enthusiasm from the wider specialty. This has been surprising, as OMFS is relatively late to starting a programme like this, but I am hopeful that this has started and will continue to shift as more data become available; it is only the participation by the specialty that will ensure the quality and success of QOMS, and I am certain that OMFS will want to remain on a par with their peers who are already much further ahead in this quality arena.

This report is an exciting first step in turning the mass of data that has already been collected into a tangible output. With the future addition of more surgeons, more units and more robust data the outputs will go from strength to strength, giving OMFS something to be very proud of, and for those who have been involved in its inception, a legacy to leave, as they will be recognised as those who made it possible for OMFS colleagues to drive improvements in the care they provide for the benefit of future patients.

Marisa Mason

Chief Executive of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

**Theodor Billroth (1829–1894), inaugural lecture as the head of the
Second Surgical Department in Vienna in 1867:**

‘He who cannot quote his therapeutic experiences in numbers is a charlatan; be truthful for clarity’s sake, do not hesitate to admit failures as they must show the mode and places of improvement.’

Royal College of Surgeons, England:

‘The objective of publishing the data is to drive forward improvements in care and enable patients to understand far more about the nature of a surgeon’s work and their recovery after an operation..... It is believed that, by revealing what others have achieved in their clinical area, surgeons are more likely to reflect on their practice and be inspired to improve while providing patients with accurate information on their surgeon’s outcomes.’

Anonymous OMFS clinician:

‘We have found the BAOMS QOMS initiative to be very supportive, empowering and highly relevant to clinical practice. The NCIP dashboard is well presented and informative, it works well when viewed within the context of a complementary dataset. We would struggle to imagine a future without QOMS in the pursuit of excellence for patients treated in our department and specialty.’



Foreword by the QOMS Team

The BAOMS QOMS initiative was conceived after the publication of the first GIRFT OMFS report in November 2018. Over the last 4 years the QOMS committee members, BAOMS SSIG leads and aligned QOMS OMFS unit have worked tirelessly to document patient care episodes which have been reported in this inaugural BAOMS QOMS report. We acknowledge the financial support BAOMS Council has provided to recruit 10 data-coordinators (for a period of 3 years) without whom such steady case ascertainment (around 3000 episodes of patient care as of July 2022) would not have been possible.

This is an important milestone for quality improvement within the specialty of Oral and Maxillofacial Surgery in the UK as such a major undertaking has not been previously attempted in this country. Most quality improvement initiatives require several years to establish themselves in normal times and it is perhaps more remarkable that colleagues within our specialty have been successful in pursuing this worthy cause whilst providing excellent clinical care within very challenging settings through the COVID-19 pandemic. Recovery of elective clinical activities is still ongoing, and variation exists between nations and regions across the UK.

The data presented within the following pages represents the entirety of our specialty's provision (excluding Cleft Lip and Palate and Craniofacial Surgery which have already established quality assurance processes) of treatment in the NHS across the three nations (England, Wales, and Scotland) within various institutional settings (University Teaching Hospitals, District General Hospitals, Major Cancer and/or Trauma Centres and spoke units supported by major hub organisations). The results presented are therefore representative of what our specialty delivers within daily practice.

You will find that within each subspecialty represented in this report, there is meaningful data which clearly reports on the treatment outcomes measured by their predetermined metrics, agreed upon by clinical experts within these areas, after months of careful deliberation and review of the body of evidence in the published literature. In the first year of the QOMS audit cycle, we demonstrate early adoption successes of our data collection platform and processes. Our datasets have been tried and tested in a multi-centred pilot which have laid down the foundations for this project.

The depth and breadth of each section varies; this could reflect the scope of each subspecialty and/or perhaps the contribution from clinical colleagues who both represent and are clinically active in these areas of practice. In order for the project to continue to truly represent the diversity of OMFS in the UK, **it is crucial that it receives the support and commitment from colleagues in the widest sense.** We hope all OMFS units will, in time, contribute accurate and contemporaneous data transparently to QOMS so that it becomes the vital clinical governance instrument which our specialty and patients deserve.

The timeline for publication of this report meant that data collected in some registries may not have been complete and/or mature at the point of data capture. There will be scope for improvement in the months and years ahead, it is all but certain that the next report published will report on a more established and mature dataset.

Looking forward, in Year 2 of the current audit cycle, QOMS will have three aims:

- **Growth:** to expand and receive data contribution from a greater number of UK OMFS units

Foreword by the QOMS Team

- **100% data capture of cases:** to embed a comprehensive system of data quality checks (principally case ascertainment and care episode completeness) which will include external case ascertainment checks with National Consultant Information Programme (NCIP) and/or direct liaison with hospital coding and information technology departments

- **Presentation of metrics:** to expand the panel of risk-adjustment processes to all parts of QOMS and develop data processing steps to improve graphical display of real-time data for surgical teams to access

Year 3 of the project will have three aims:

- **Consolidate the registries:** to expand the embed registries for TMJ, virtual planning cases including patient specific mandibular implants, benign tumours of the jaws and salivary gland cancers
- **Clinical governance processes:** to draw on senior clinical leadership and develop clinical governance processes that highlight where excellent care is seen and offer 'support and guidance processes' for units who could benefit with constructive support
- **Financial sustainability:** to explore funding options, for example by adopting a licence/subscription model open particularly to non-OMFS UK-based surgeons engaged in Head and Neck surgical activity and/or non-UK OMFS surgeons seeking to record and measure clinical outcomes benchmarked to UK OMFS peers

The reported findings have sufficient published outcomes for colleagues to engage with their local departments and multidisciplinary teams to initiate the next phase of the initiative at a local, regional, and national level, to now identify how we can all improve our service. The findings reported thusfar have met the requirements of each subspecialty's metrics and delivered on the GIRFT recommendation to develop a patient-focused outcomes audit programme for oral and maxillofacial surgery.

We are reminded of the adage, ascribed to Charles Goodhart, known as the Goodhart's Law

"When a measure becomes a target, it ceases to be a good measure."

which we believe speaks of the sometimes unintended consequences of deciding to measure. Surgeons are humans and may be affected by the anxiety about unwanted scrutiny. At the earliest stage of this process, we appeal for colleagues to consider the myriad of reasons why early findings in this report should not be taken as gospel; much further reflection and governance processes need embedding, alongside constructive debates, before the findings presented should be considered weighty enough to drive changes in practice. Thus, at this time, no distortion in clinical practice is indicated.

QOMS, as a specialty-led audit, has developed nearly 30 years after the equivalent programme started in cardiothoracic surgery, as a response to the Bristol Heart Inquiry. When the Consultant Outcomes programme was introduced in 2013 (by Jeremy Hunt, then Secretary of State for Health), it was in a context of mature audits in the surgical specialities of the UK, most of which had data collection processes, national coverage, risk-adjusted outcomes, data validation

Foreword by the QOMS Team

processes and annual reporting underway. OMFS was the exception, and our specialty is now in a 'race to catch-up' in this process.

We demonstrate a specialty-led choice of pertinent metrics, pilot risk-adjustment processes and presentation of benchmarked data in a user-friendly report. We support this annual report with easy accessed graphics including live dashboards on the online REDCap data-collection portal. This includes a novel application of a risk-adjusted 'free tissue transfer success' control process graphic (Cumulative Sum Chart) that will be available online in early 2023, which compares unit-activity against national activity, which should be of interest to reconstructive surgical specialities worldwide.

The nature of specialty led selection of metrics, bespoke metric risk adjustment processes and live dashboards, are several of many features which set this project apart from the NCIP programme. The QOMS process involves a BAOMS appointed project manager, currently 10 funded data coordinators in affiliated units and OMFS clinical leads in those units with communication channels to the project steering group. The professional, self-governing, clinician-led process aims to be patient centred by capturing activity that is closely linked to our patients' quality of life and quality of care. NCIP in contrast captures consultant level data reflecting case-volume analytics. NCIP seeks to answer to centralised government requirements and metrics, which do not currently consider complexity of patient need or the variety of OMFS surgical interventions. NCIP data is narrowly focused on patient flow (length of stay metrics and readmission data) and safety (mortality data), many of which are near un-informative when applied to aspects of routine OMFS activity.

QOMS strengths need to be nourished if clinician-involvement is not to be our 'Achilles' heel'. We argue that a healthy transparent responsive quality improvement programme, run by BAOMS, is a good tool to question, challenge or corroborate findings from NCIP. Without knowing the funding future of NCIP, we judge a specialty led programme 'in charge of its own destiny' is a sensible investment by BAOMS in order that OMFS units can increasingly demonstrate 'kite-marking' of the breadth and quality of OMFS services offered throughout the UK. This information can be demonstrated to commissioners when required.

So QOMS and NCIP are different entities however we believe our differences are vital and complementary in providing a fuller picture of unit activity. Indeed, our differences need not imply separateness; in our efforts to validate the completeness of data entry to the BAOMS QOMS dataset, we are collaborating with the NCIP team to establish processes to affirm 'denominator validation' using real-time data to assure optimal case ascertainment. This promises to improve credibility and accuracy of data presented and may in the future reduce the burden of data collection, thus allowing improved time usage of data coordinators, increasing sustainability of their endeavours, and perhaps expansion of QOMS into new areas of interest at no extra cost.

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BAOMS QOMS Clinical Lead

David Tighe
BAOMS QOMS Deputy Clinical Lead

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BAOMS QOMS Project Manager

The findings and recommendations of this report are applicable to most if not all OMFS units in the UK. In all the subspecialties involved in BAOMS QOMS within this cycle, the datasets are unique and innovative as they represent the first set of data contributed by multiple units in the three UK nations: England, Scotland and Wales. As data matures in the coming years the depth of future analysis will provide even more detailed, meaningful data and hopefully deliver secondary analysis suitable for peer-reviewed publications to enable wider dissemination of the output produced by the time and effort invested by the entire BAOMS QOMS initiative while showcasing UK OMFS as a leader in quality improvement with the specialty on a wider scale.

The main findings and recommendations for each of the subspecialties are:

1. Oral and dentoalveolar surgery

Metrics selected as indicator of performance:

- Appropriateness of tier attribution
- The management of oro-cervical infection

Summary

- Almost 85% of the referrals to OMFS units could have been managed in the community by the Tier 2 service (58.6%) or by their Primary Care Dentist (27.4%)
- Factors which influence access to primary care dentistry and the quality of treatment provided: timeliness of attendance and/or intervention, accuracy of diagnosis and efficacy of treatment received, could all contribute to the need to receive further intervention in patient who present with oro-cervical infection to OMFS units
- The management of oro-cervical infection in OMFS units are often complex, costly and have health/socio-economic implications for the population

Recommendations

- Benign soft tissues (e.g., mucocoeles/polyps/warts) referrals are potential conditions that could be managed in the primary care provided there is appropriate experienced Tier 1 or 2 clinicians working

within the governance framework of a managed clinical network with OMFS consultation and oversight. This would require the collaborative support of pathology reporting services with clear and detailed alert systems in place for any unexpected diagnosis of malignancy with the input of the relevant Head and Neck multidisciplinary teams

- There is sufficient information gathered in these two data collection cycles to support the need for OMFS units involved to review the service provision in their catchment areas with the commissioners and local dental committees
- The questionnaire for management of oro-cervical infection section of QOMS will be refined and more OMFS units will be encouraged to participate to provide a wider picture to account for regional variations and compare the outcomes in the 4 nations who have some differences in their provision of primary dental care

2. Oral and maxillofacial trauma

Metrics selected as indicator of performance:

The operative treatment of mandibular fractures

- Unexpected returns to theatre
- Unplanned readmissions

The operative treatment of orbital floor/wall fractures

- Unexpected returns to theatre
- Unplanned readmissions
- Visual problems and enophthalmos

Summary

- In the treatment of mandibular fractures, the return to theatre rate was low (1.2%) with an even lower unplanned readmission rate
- In the treatment of orbital floor/wall fractures, 3% of patients developed complications prior to hospital discharge and 6% of patients required readmission within 90 days of surgery
- 3% of patients developed post-operative visual problems or diplopia within 90 days of surgery

- There was no documented data entry for whether patients had pre-treatment cross sectional imaging and ophthalmology assessment for 22% of patients

Recommendations

- The dataset collected has provided the basis for development of risk adjustment in mandibular trauma treatment. The dataset could perhaps be further revised to ensure that it remains simple and as accurate as possible in providing information to measure the clinically relevant metrics for QOMS which may benefit from reappraisal in view of the emergence of NCIP for OMFS
- Pre-treatment assessment and evaluation of orbital floor/wall fractures will require further investigation to ascertain whether the data presented represents genuine variation in practice (potential scope for education and training) or scope for improvement in data collection in QOMS OMFS units

3. Orthognathic surgery

Metrics selected as indicator of performance for LeFort I and mandibular bilateral sagittal split osteotomies:

- Unplanned returns to theatre
- Unplanned readmissions following discharge from hospital
- Hospital length of stay following surgery

Summary

- Overall treatment of patients with dentofacial deformity in the QOMS OMFS units had very low early complication rates – 2% return to theatre within 30 days
- Median length of stay was 1 day
- The number of patient cases reported in the series has been lower than projected due to the impact of COVID-19 on multiple OMFS units, at the time of writing, the provision Orthognathic Surgery has just been restarted after a significant period of pause in some centres

Recommendations

- As NHS elective treatment recovery progresses, the increased throughput in orthognathic surgery will provide a more accurate picture of practice in this subspecialty - the higher number of patients registered into the audit with more mature data will hopefully provide a larger and more detailed dataset to further

test the metrics selected to measure performance of OMFS units in the next report

4. Non-melanoma skin cancers in the head and neck

Metrics selected as indicator of performance:

- Rate of diagnostic biopsy
- Surgical margins
- Site of cutaneous malignancy
- Unplanned reoperations

Summary

- Dermoscopy was used in 30% of the BCCs and 33% of the SCCs; however, a significant percentage of patients had pre-operative biopsies (36% for SCCs and 20% of BCCs). This approach adds significant cost and additional treatment delays, which are exacerbated by the volume of skin cancer patients
- The location of the primary tumours was found to be in accordance with the literature, with scalp and ear being the dominating areas for SCCs and nose-cheek being the most common locations for BCCs
- Involved deep margins (<0.5mm) were found in 19% of the cases, in 38% of the tumours, the deep margin was <1mm
- The data collected observed under reporting of the clinical T stage for SCCs. This has importance implications on surgical planning; the T stage is included in the updated BAD guidelines as a criterion for selecting the predetermined surgical margin which can contribute to the resection marginal clearance of skin cancers (1)
- Primary closure was the commonest method of wound repair (45% of lesions)
- The re-operation rates reported were low (2% overall and <0.5% within 30 days of surgery)

Recommendations

- Preoperative biopsies can be avoided in most cases, as the diagnostic accuracy of dermoscopy has been shown to be well over 80% when performed by adequately experienced clinicians. (2) There is a scope to promote dermoscopy training amongst OMFS skin cancer surgeons. There are several intensive customised dermoscopy courses; the BAOMS (through the skin SSIG) can guide clinicians towards them

- Ideally, data collection should be continuous (due to the volume of activities of non-melanoma skin cancers data was collected over 2 two-month periods of time over the course of a calendar year), however there are implications of workload on data co-ordinators and the local clinicians
- Clinical T stage for SCCs and predetermined margins under-reported in this dataset highlights the potential need to revisit the fundamentals of skin cancer staging and its implications on treatment and outcome to the clinical teams
- The project has not collected information about adjuvant treatment (radiotherapy), the relevance and need for this will be reviewed in the next iteration of the NMSC QOMS dataset

5. Oncology and reconstruction in the head and neck/maxillofacial region

Metrics selected as indicator of performance:

- Oncology
 - Complications within 30 days of surgery
 - Lymph node harvest in a staging / therapeutic neck dissection
 - Surgical Margin Status (positive margin <1mm)
- Reconstruction
 - Free flap outcomes
 - Length of hospital Stay
 - Time from surgery to commencement of adjuvant treatment

Summary

- QOMS Oncology and Reconstruction registry can be judged a cautious success. This audit, at an early stage, is demonstrating characteristics of a specialty led robust, fair and sustainable system of quality governance
- Data quality is acceptable (>95%) throughout most fields with some exceptions (missingness in flap monitoring (26%) and adjuvant treatment (40%))
- A complication rate of 40% is close to previously published benchmarking papers
- The positive margin rate was 14% with a predicted positive margin rate of 11% after risk adjustment

- Delay to adjuvant treatment was frequent, with 12% of patients making the 42-day target. The data analysed suggests that perhaps with the current working arrangements and resources available, the NHS perhaps is falling short of this standard/important cut-off timeline
- The average length of stay for patients who had head and neck reconstruction was 20 days and the predicted average length of stay after risk-adjustment was 10 days
- The aggregate frequency of extended length of stay >50days was 2% in this phase of the national audit
- The overall flap success rate for the dataset was 96%
- 95% of patients were discharged back to their residence
- 7% of patients are recorded as deceased on 6-week follow-up
- Despite the 1160 entries reported, majority of these cases came from 5 units, 3 of whom receive financial support to fund QOMS data co-ordinators

Recommendations

- We propose the addition of a further target, 56 days which may be more suitable for the cases delayed by the need to de-calcify bone resections. 43% of patients met the 56 day treatment target
- An alternative metric for consideration could be, again at the 5% threshold, extended length of hospital stay of > 50 days
- Two centres have contributed data for more than 100 free flap patient cases thus far in QOMS oncology and reconstruction registry, thus conclusions about performance should wait until the confidence limits are narrower
- Data collected within QOMS should be used in conjunction with NCIP portal data which has the advantage of input from the Office of National Statistics for community/out of hospital mortality
- Data collection and verification by OMFS QOMS units will need to ensure that data completion and verification is of the highest standard with engagement of the local clinical team supported by the data co-ordinators

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Inception of BAOMS QOMS

The Getting It Right First Time (GIRFT) programme was set up in 2012 by Professor Tim Briggs. GIRFT was designed to improve the treatment and care of patients through in-depth review of services, benchmarking, and presenting a data-driven evidence base to support change. The GIRFT workstream for oral and maxillofacial surgery (OMFS), led by Ms Maire Morton, published in the specialty's 1st GIRFT report (November 2018) a series of recommendations to improve quality of OMFS surgical care. (3) The GIRFT review highlighted the lack of both consensus on appropriate measures and systematic data collection indicative of effectiveness or quality of care across OMFS.

Reflecting on these realities, the BAOMS President then, Mr Ian Martin, with support from Council, dedicated his presidential initiative to the creation of a systematic quality improvement programme across the specialty to demonstrate that effective care is provided and to promote the continued successful development of OMFS care in the NHS.

In July 2018 at a meeting convened by BAOMS, the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) project was launched as the Association's quality improvement and clinical effectiveness programme for OMFS. The meeting included members of the BAOMS Council, leads and deputy leads of the Subspecialty Interest Groups (SSIG) to discuss the form QOMS should take and decide of a workable timeline. BAOMS had also invited speakers from other Associations, Societies and Working Groups of established quality improvement initiatives to share their experience in surgical and clinical audits.

Development – Phase 1

Following a three-month consultation with the BAOMS membership, the BAOMS SSIG leads, and deputies were invited to develop QOMS and the conditions, procedures and initial quality-of-care indicators were selected (*Table 1.1*). The subsequent development phase of QOMS, which included writing up the Project Protocol and designing the 1st data collection tools, culminated with a consented,

QOMS subspecialties, conditions, procedures, and quality-of-care indicators

Table 1.1

Procedures	Conditions	Metrics	Data collection
Oncology			
Resection (±reconstruction)	All oral cavity and oropharynx SCC	Margins	Continuous
Elective or therapeutic lymphadenectomy	Previously untreated primary oral cavity or oropharynx SCC	Number of lymph nodes	
Major head and neck surgery	Head and neck cancers	Unexpected return to theatre (RTT) (In-hospital mortality)	
Reconstruction			
All tissue transfer	All	Length of stay (LoS) and Flap survival	Continuous
Head and Neck / Maxillo-facial Reconstruction	Oral and Head and Neck cancers	Time to commencement of adjuvant radiotherapy if required	
Non-melanoma skin cancers			
Complete excision	BCC and SCC	Rates of biopsy Excision margins Site of tumours (indicator of case mix complexity) Complications / Infection	Biannual two-month periods
Oral and dentoalveolar surgery			
Dentoalveolar surgery	All	Appropriateness of tier attribution Infections	Annual two-month periods
Trauma			
Mandibular fracture & Isolated orbital wall fracture	All	Unexpected RTT Readmissions Visual complications (orbital wall fractures only)	Continuous
Orthognathic surgery			
Le Fort I and Mandibular ramus osteotomy	All	Patient-reported outcomes Unexpected RTT Readmissions LoS	Continuous

INTRODUCTION

proof-of-concept pilot in six OMFS units in England to trial the project's set-up, between December 2019 and April 2020. Its purpose was primarily to test the feasibility of the audit questionnaires and their effectiveness with regards to quality improvement, to pilot the processes associated with the data collection, and to provide baseline data to support applications for patient data collection without the requirement of prospective consent.

The pilot demonstrated that: the data collection system selected for QOMS was easy to use and user-friendly; the questionnaires needed to be revised to better match data collection processes in hospitals: the volumes of some high throughput OMFS activities were perhaps not suitable for continuous data collection; relying exclusively on surgeons to collect data would not be sustainable in the long term thus alternative solutions should be sought and finally, that the need of prospective individual patient consent increased the complexity of the process and was a barrier to sustainable data collection. The pilot had to be concluded a few weeks earlier than planned at the onset of the COVID-19 pandemic.

Development – Phase 2

Over the pandemic lockdowns (2020-2021), the issues identified in the pilot were addressed. First, the team was expended to create subspecialty-specific audit groups

led by consultants supported by junior colleagues. Their task was to review and improve the questionnaires for each audit. It was decided that OMFS activities with high throughput (e.g., oral and dentoalveolar, non-melanoma skin cancers) will have annual/biannual two-month periods of data collection as this would reasonably provide adequate data and continuous audit was not sustainable. The other major finding of the pilot was that consenting patients prospectively was not sustainable and constituted a barrier to the success of the project. Where possible, the solution was to apply to UK devolved administrations to obtain approval to collect patient information without consent.

The largest development in that phase was the decision by BAOMS to offer financial support to ten OMFS units in the country to appoint a part-time data coordinator to manage local data collection to improve coverage and data quality. OMFS units in the UK were invited to apply for this funding through an application form to evidence the record of engagement in prior quality improvement initiatives and were selected by the project team and BAOMS Council Trustees (*Table 1.2 and Figure 1.1*).

This phase transitioned to the project's national roll-out, which was open to all OMFS units, in the summer of 2021. This data collection period will run for three years (2021-2024) and constitutes the 1st QOMS cycle.

BAOMS-funded OMFS departments

Table 1.2

Trust / Health Board	Region	Hospital type	Start date
Betsi Cadwaladr University Health Board	North Wales	District General Hospital	January 2022
East Kent Hospitals University NHS Foundation Trust	Southeast Coast	District General Hospital	August 2021
East Lancashire Hospitals NHS Trust	Northwest	University / Teaching Hospital	October 2021
King's College Hospital NHS Foundation Trust	South London	University / Teaching Hospital	July 2021
London NorthWest University Healthcare NHS Trust	London North	District General Hospital	March 2022
Leeds Teaching Hospitals NHS Trust	Yorkshire & Humberside	University / Teaching Hospital	July 2021
Liverpool University Hospitals NHS Foundation Trust	Northwest	University / Teaching Hospital	January 2022
South Tyneside and Sunderland NHS Foundation Trust	Northeast	District General Hospital	August 2021
Swansea Bay University Health Board	South West Wales	University / Teaching Hospital	August 2021
University Hospitals Birmingham NHS Foundation Trust	West Midlands	University / Teaching Hospital	July 2022

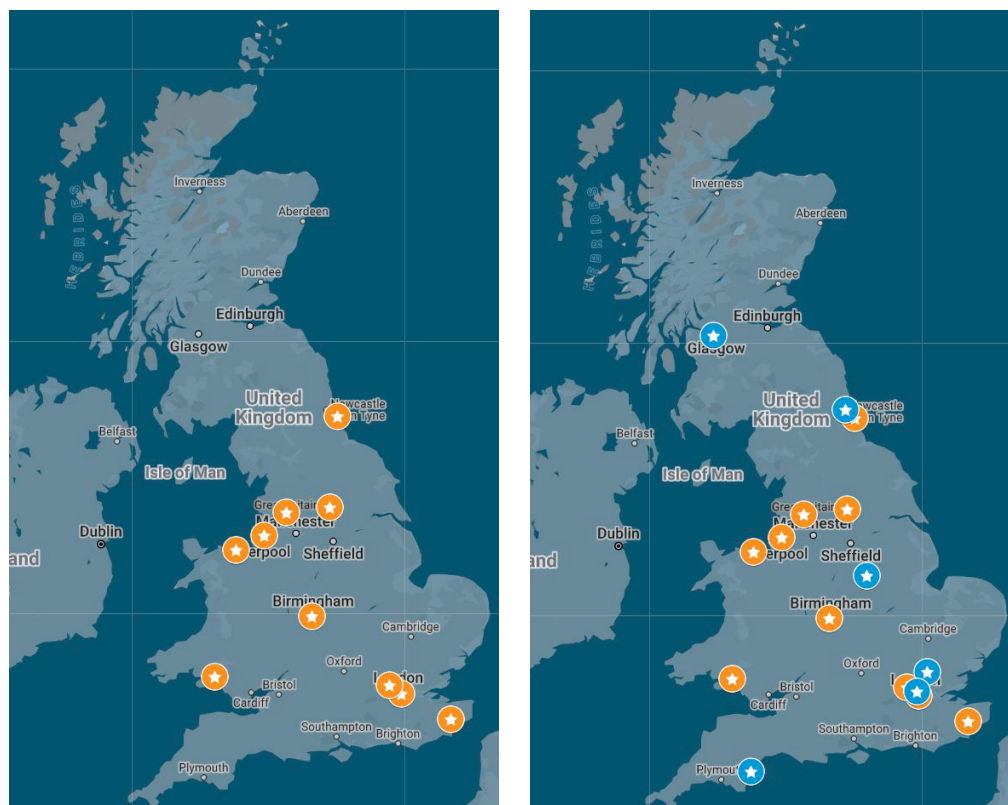


Figure 1.1

Map of BAOMS-funded OMFS departments (left) and of contributing OMFS departments by June 30th, 2022 (amber – BAOMS funded data co-ordinators; blue – self-funded data collection)

QOMS aim and objectives

The overall aim is to set up and develop a sustainable quality management and clinical effectiveness programme for OMFS. QOMS should deliver continuous improvement in the care of patients undergoing OMFS within all parts of the NHS and demonstrate health-related benefits to patients of selected OMFS activities.

QOMS proposes to achieve this aim

- By developing benchmarks for the selected quality-of-care indicators and by promoting quality improvement activities as part of a quality management system to measure quality of care in OMFS
- By developing practice-based evidence for the management several rare conditions (e.g., odontogenic tumours of the jaws and salivary gland cancers), for which randomised-controlled trials would perhaps not be feasible
- By promoting clinicians’ participation in the programme and supporting their appraisal and revalidation process

- By encouraging secondary research (e.g., data mining, modelling) of the QOMS data with oversight from the BAOMS QOMS executive team and BAOMS council

Description

QOMS has a patient-centred approach. The project has been developed by and for use of OMFS clinicians and focuses on indicators relevant to their practice. In time, QOMS will produce comparative data at hospital level to enable feedback to the clinicians to inform their practice and future recommendations for service improvement.

QOMS should foster improvement and be responsive. Once established, QOMS is an iterative project and has been designed to follow a 3-year cycle, thought to be sufficient to measure quality of care (Baseline, year 1), utilise data for local service improvement (Quality improvement, year 2) and ensure that changes are maintained and working (Implementation, year 3). At the end of each cycle, the conditions, procedures, and indicators are reviewed and will be refined in parallel to the evolution of clinical practice. Any indicator of quality of care must serve a purpose and follow the SMART

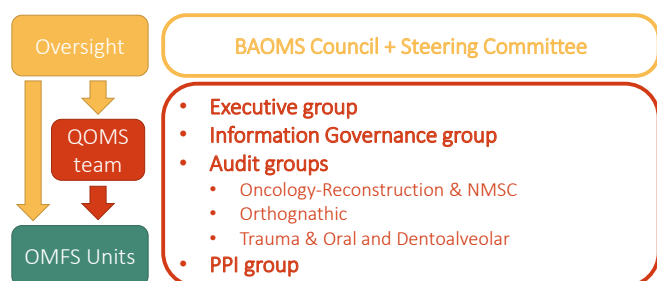
INTRODUCTION

principle (Specific, Measurable, Actionable/Achievable, Relevant, and Timely).

QOMS is led by an independent team and overseen by its Steering Committee and the BAOMS Council (see Figure 1.2). The former ensures that QOMS is progressing and consistently meets its objectives while the latter ensures that the values and principles of the Association are adhered to by the project.

Figure 1.2

BAOMS QOMS Governance Structure



Information governance. Applications to collect patient identifiable information without consent was submitted to the devolved administrations:

- Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) in England and Wales. The process is known as Section 251 support and approval was obtained in December 2020
- Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) in Scotland. Approval was obtained in May 2022

For UK nations where a similar process is not available (Northern Ireland) or for interim period before obtaining approval (Scotland), information governance for QOMS would have to rely to local Trusts’ or Health Boards’ approvals for anonymised data collection.

Participating OMFS departments have flexibility with regard to their consent to participation in QOMS and would retain ownership of the data they have contributed to the project. They should be led locally by a QOMS clinical lead (at the consultant level) supported by a deputy lead and where possible a data coordinator (background of personnel varies depending on local preference and/or availability) for data collection and entry.

This document reports the results of the 1st year of data collection. In the early phase of this project some subspecialties have been able to produce anonymised hospital-level comparative data, the analysis includes the focus on data quality and completeness to ensure QOMS continues to develop and progress in the right trajectory.

Material and methods

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Online system

Data collection is performed via a web-based interface and data is stored in secure servers. The information technology solution selected to collect and store data for QOMS is the Research Electronic Data Capture (REDCap) system (<https://www.project-redcap.org/>). (4,5) REDCap was created by researchers at the University of Vanderbilt in Nashville, Tennessee. REDCap is a secure web application for building and managing online surveys and databases. It was specifically developed to support online and offline data capture for research studies and operations. REDCap is an “off-the-shelf” system that offers flexibility for developing data collection tools, managing and reporting data. REDCap is managed locally through an institution part of the REDCap consortium. Our partner is the Barts Cancer Research UK Centre at Queen Mary University of London (BCC, QMUL).

Data storage and access

QOMS collects both patient identifiable information (England, Wales and Scotland) and sensitive information, which are confidential. Data is stored in secure servers, located in the UK, and managed by the BCC, QMUL.

Data access relies on the following access control rules. First, REDCap access is not provided at the team level but to individuals, who must have a direct relationship with QOMS (i.e., participating staff from a participating hospitals). Each individual is given a unique username and password. Each user’s access is limited to the registries they are contributing to and to the data entered at the institution(s) where they are based. Secondly, the BCC is a third-party organisation providing the IT solution for QOMS. Some staff members have access to the data, but this is limited to specific and pre-defined purposes (e.g., database maintenance and/or data recovery) as described in the Service Level Agreement between QMUL and Saving Faces (SF). Finally, members of the QOMS Team do not have access to patient identifiable information, with the exception of the designated data manager (DDM). The DDM is a non-clinical member of the QOMS project team trained in data and security protection and BCC Safe Haven policies and procedures and subject to the BCC Safe Haven security monitoring and controls. Any processing of patient identifiable information must be performed by the DDM within the BCC Safe Haven environment, accessed via the Citrix interface (i.e., a virtual desktop within that environment).

REDCap version: REDCap 11.1.27 - © 2022 Vanderbilt University

Participating units

(See Figure 1.1 right)

Analysis

We are aware that data collected within the project to date is mostly early data and the ability to produce reliable comparative data at the unit level is still in development. Therefore the 1st analysis of data held by QOMS includes assessment of data quality (missing data and outliers) in order to evaluate its impact on the production of hospital-level risk-adjusted outcomes. This will be fed back to participating hospitals with view to improve the data collection processes and the quality of data collected for subsequent analysis.

Secondary aims of this report include preliminary correlations between risk / surgical factors and outcomes. This aspect of the initiative remains at its infancy. Its feasibility and accuracy will be tested, and the project team is optimistic that this process will be useful to perform power calculations to establish thresholds of sample sizes to reach to inform the optimal time point for further analysis in subsequent reports.

The analysis is mostly descriptive with the exception of the Non-Melanoma Skin Cancer and, Oncology and Reconstruction where sections about risk adjustment have been developed. The analysis covers the data collection period from of the second phase of the project (dates vary according to departments) to summer 2022 (Table 2.1).

Table 2.1

Data collection period considered for analysis

Registries	Data collection	
Oral and Dentoalveolar	(1) Appropriateness of Tier Attribution (2) Infection	Jan-Feb 2022 Jan-Feb 2022
Trauma	Mandible fractures Isolated orbital wall fractures	Continuous (up to July 2022) Continuous (up to July 2022)
Orthognathic surgery		Continuous (up to July 2022)
Non-melanoma skin cancers		Mid-Sept to mid-Nov 2021
Oncology & Reconstruction		Continuous (up to Aug 31 st , 2022)

Further resources are available on the [QOMS page of the BAOMS website.](#)

Organisational questionnaire

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Hospitals which collected data in the 1st year of the QOMS Project (2021-2022) were asked to complete an organisational questionnaire. This questionnaire provides information with regard to the scope of services provided which are linked to the number of registries each unit would contribute to data entry. Thirteen questionnaires were returned, one of which had to be excluded due to incomplete dataset. The organisational questionnaires are important to provide an overview of the scope of clinical activities and coverage of the project's initiative to ensure good representation from various types of OMFS units in the participating UK nations. The information provided includes the estimated annual throughput of activities captured by the QOMS audits, multidisciplinary team set-up and standard practice in aspects of treatment related to the QOMS audit (e.g., trauma imaging practice and care for oncology and/or reconstruction patients after surgery).

In the reporting of the organisational questionnaire responses, in several audits there is a mismatch between the numbers of units actively engaged with QOMS for the respective subspecialty compared to that of returned questionnaire. This was due to either to the ability of each unit to engage with QOMS (e.g., non BAOMS-funded units where parts of the practice scope were not included in QOMS) or delays in data contribution due to local factors e.g., information governance/set-up issues, workforce challenges in employing data co-ordinator or COVID-19 related impact on service recovery.

General characteristics of participating OMFS units

Units which participated to QOMS in 2021-2022, were in England (n=9), Wales (n=2) and Scotland (n=1).

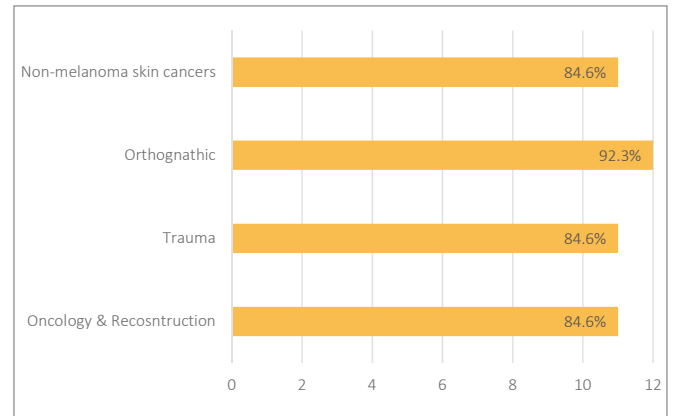
Participation to QOMS registries varied between the units (Figure 3.1).

11 hospitals participated to the Oncology and Reconstruction (OR) registry (one of them does not perform reconstruction surgery due to service organisation / setup, their data has not been included), 11 to the Trauma registry, 12 to the Orthognathic Surgery registry and 11 to the non-melanoma skin cancer registry.

Units were classified as University (Teaching) Hospitals (n=7), District General Hospitals (n=5, 4 Hubs and 1 Spoke) (Table 3.1 on next page). Overall, the median number of full-time equivalent OMFS consultants was 8 (range: 4-17), 10 were Cancer Centres and 8 Major Trauma Centres.

Figure 3.1

Overall participation to QOMS Registries



Oncology and Reconstruction

Number of units which participated to QOMS: 11

Number of units which returned the organisational questionnaire: 10

The overall number of oncology-reconstructive surgeons varied between 2 and 6 (full-time equivalent, median = 4) with 0-6 (median=3.5) in the 'hub' unit and 0-5 (median=0) in the 'spoke' unit.

The Head and Neck MDT included a restorative dentist in 9 units and a representative of the anaesthetic team in 4 units.

The typical annual number of major reconstructions done varied between units and postoperative care for free flap procedures mainly relied on HDU/ICU support (Table 3.2 on next page). Temporary tracheostomy rates varied, and this could be related to the level of postoperative care available to each unit (Table 3.2 on next page) Finally, the estimated frequency of cancellation rate due to lack of ICU/HDU beds varied between 0 and 10 times a year (median = 3.5). One of the departments reported that their postsurgical care pathway could change depending on ICU capacity, which affected tracheostomy rates and cancellation of operations.

Sentinel lymph node biopsy for early OSCC was available in 7/11 units. Service expansion in the future will include SLNB in at least 2 additional hospitals.

Details of Oral and Maxillofacial Surgery Units participating in BAOMS QOMS

Table 3.1

Trust, Health Board or Hospital name	Number of full-time equivalent OMFS consultants	Type of OMFS unit?	Cancer Centre?	Major Trauma Centre?	Participation in audits			
					OR	Trauma	OS	NMSC
Betsi Cadwaladr University Health Board	5	DGH (Hub)	Yes	No	Yes	Yes	Yes	Yes
East Kent University Hospital NHS Foundation Trust	7	DGH (Hub)	Yes	Yes	Yes	Yes	Yes	Yes
East Lancashire NHS Trust	9	University (Teaching) Hospital	Yes	No	Yes	Yes	Yes	Yes
Greater Glasgow and Clyde Health Board	8	University (Teaching) Hospital	Yes	Yes	Yes	Yes	Yes	Yes
King's College NHS Trust	9	University (Teaching) Hospital	No	Yes	No	Yes	Yes	Yes
Leeds Teaching Hospitals NHS Trust	11	University (Teaching) Hospital	Yes	Yes	Yes	Yes	Yes	No
London Northwest NHS Trust	10	DGH (Hub)	Yes	Yes	Yes	Yes	Yes	Yes
Liverpool University Hospitals NHS Foundation Trust	17	University (Teaching) Hospital	Yes	Yes	Yes	Yes	Yes	Yes
Queen's Medical Centre, Nottingham	8	University (Teaching) Hospital	Yes	Yes	Yes	Yes	Yes	No
South Tyne & Sunderland NHS Trust	6	DGH (Hub)	Yes	No	Yes	Yes	Yes	Yes
Swansea Bay University Health Board	6	University (Teaching) Hospital	Yes	Yes	Yes	No	Yes	Yes
Torbay Hospital	4	DGH (Spoke)	No	No	No	Yes	Yes	Yes
University College Hospital	5	University (Teaching) Hospital	Yes	No	Yes	No	No	No

(OR: Oncology and reconstruction, OS: Orthognathic surgery, NMSC: Non-melanoma skin cancers)

Oncology service set-up and practice trends in OMFS units participating in BAOMS QOMS

Table 3.2

Trust, Health Board or Hospital name	Number of full-time equivalent oncology-reconstructive surgeons in unit	Number of full-time equivalents employed by 'hub' unit	Number of full-time equivalents, employed by 'spoke' units i.e., visiting to 'hub' for surgery	A restorative dentist is a core member of Head and Neck MDT?	A representative of the anaesthetic team is a core member of Head and Neck MDT?	Post-operative care destination for free flap	Temporary tracheostomy performed for free/pedicled flaps - estimated percentage of patients	Frequency of cancellations due to lack of ICU/HDU beds (times/year)	Sentinel lymph node biopsy for early OSCC
Betsi Cadwaladr University Health Board	3	3	0	Yes	No	ICU (Level 3)	<50%	5	Yes
East Kent University Hospital Foundation Trust	5.5	5.5	0	Yes	No	ICU (Level 3)	<25%	2	Yes
East Lancashire NHS Trust	2	0	0	Yes	Yes	HDU (Level 2)	>75%	0	Yes
Greater Glasgow and Clyde Health Board	6	4	2	Yes	No	HDU (Level 2)	>50%	6	Yes
Leeds Teaching Hospitals NHS Trust	5	5	0	Yes	Yes	HDU (Level 2)	<50%	8	No
Liverpool University Hospitals NHS Foundation Trust	6	6	0	Yes	Yes	HDU (Level 2)	>75%	6	Yes
London Northwest NHS Trust	5	5	5	Yes	No	PACU	<25%	0	Yes
Queen's Medical Centre, Nottingham	2	1	1	No	No	HDU (Level 2)	>75%	10	No
South Tyne & Sunderland NHS Trust	3	3	0	Yes	No	ICU (Level 3)	<25%	1	Yes
Swansea Bay University Health Board	2	0	0	Yes	Yes	ICU (Level 3)	>75%	2	No

ORGANISATIONAL QUESTIONNAIRE

The organisational questionnaire included 3 items for post-surgical care (Table 3.3)

In addition to clinical examination, several methods of adjunctive flap monitoring were used in most units (hand-held Doppler n=8/10 and invasive monitoring n=9/10).

Most units had either comprehensive or partial ERAS

programme for their head and neck cancer/reconstruction patients who had undergone major surgery.

Primary oral rehabilitation/implants assessment was carried as standard practice (n=5) or in a selected group of patients e.g., good prognosis, early disease (n=3). Lack of expertise was the reason given when primary oral rehabilitation/implants assessment was not carried out.

Oncology service set-up and practice trends in OMFS units participating in BAOMS QOMS

Table 3.3

Trust, Health Board or Hospital name	Number of major reconstructions done	Additional flap monitoring (Hand-held Doppler)	Additional flap monitoring (Invasive monitor (e.g., implantable Doppler))	ERAS programme *	Primary oral rehabilitation/implants
Betsi Cadwaladr University Health Board	21-30	Yes	Yes	3	No, regular/reliable access
East Kent University Hospital Foundation Trust	31-45	Yes	Yes	2	Yes, in a selected group of patients e.g., good prognosis, early disease
Greater Glasgow and Clyde Health Board	>60	Yes	Yes	1	Yes, assessment carried out routinely as standard care
Leeds Teaching Hospitals NHS Trust	46-60	No	Yes	2	Yes, assessment carried out routinely as standard care
London Northwest NHS Trust	>60	No	Yes	2	Yes, in a selected group of patients e.g., good prognosis, early disease
Liverpool University Hospitals NHS Foundation Trust	>60	Yes	Yes	2	Yes, in a selected group of patients e.g., good prognosis, early disease
Queen's Medical Centre, Nottingham	46-60	Yes	No	1	No, regular/reliable access
South Tyne & Sunderland NHS Trust	31-45	No	Yes	1	Yes, assessment carried out routinely as standard care
Swansea Bay University Health Board	31-45	Yes	Yes	2	Yes, assessment carried out routinely as standard care
East Lancashire NHS Trust	>60	No	No	1	Yes, assessment carried out routinely as standard care

* ERAS programme: 1 - structured/comprehensive, 2 - components of ERAS i.e., not formalised, 3 - No)

Trauma

Number of units which participated to QOMS: 10

Number of units which returned the organisational questionnaire: 11

The organisational questionnaire looked at 4 general themes for Trauma.

- **Service organisation:** there was a dedicated elective trauma operating lists available in 6/11 units, a fast track to acute operating list on specified days in 6/11 units and no elective/fast track access to acute list in 3/11 units
- **Treatment of OMFS fractures** (acute/elective and day case vs. inpatient) (Table 3.4)

Table 3.4

Treatment of OMFS Trauma (out of 11)

Types of injury	Acute	Elective	Day case	Inpatient
Mandibular fractures	11	0	5	7
Zygomatic complex fractures	2	10	4	8
Orbital floor/wall fractures	2	10	11	10

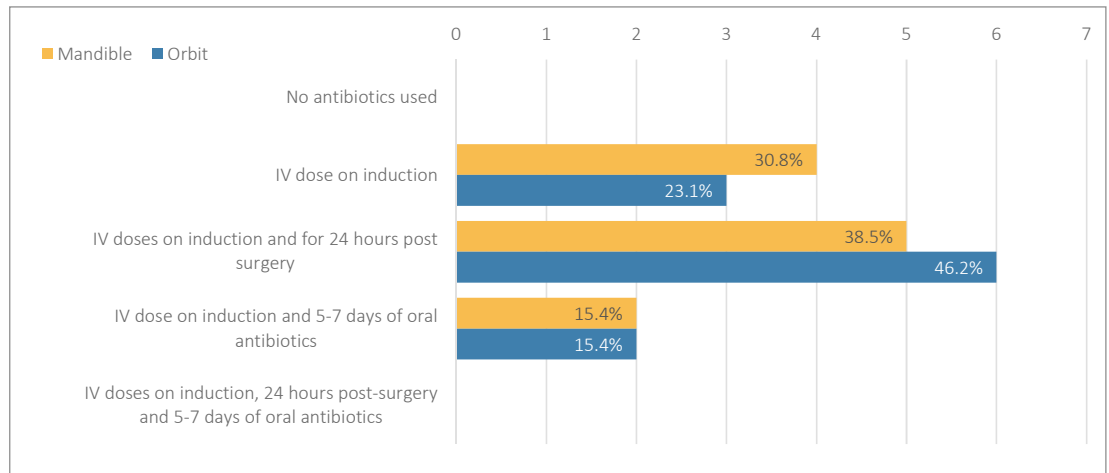
- **The pattern of prophylactic antibiotic prescription** for the operative management of mandibular and orbital fractures varied between surgical units (Figure 3.2 on next page)
- **Use of imaging.** When postoperative radiographs for patients who have had open reduction and internal fixation (ORIF) mandibular fractures with a good dental occlusion were obtained (n=8), they were all done prior to hospital discharge (n=8)

● Intraoperative CT and/or navigation in the surgical management of orbital fractures was not standard practice in any of the units. Postoperatively, imaging for

patients following exploration and reconstruction of orbital floor/wall fractures was performed in 3 units (conventional CT or single occipitomeatal (OM) view)

Use of antibiotics for mandibular and orbital fractures

Figure 3.2



Orthognathic surgery

Number of units which participated in QOMS: 8

Number of units which returned the organisational questionnaire: 12

The number of facial deformity/orthognathic surgeons in each participating unit varied from 1-8 (median=2) full-time equivalent surgeons.

The number of full-time equivalent orthodontists in MDT clinics varied from 1.5 to 13 (median 3). The number of orthognathic surgical procedures (pre-COVID) varied from 10 to 180 per year. Activity was severely affected by the COVID-19 pandemic, with hospitals reporting a substantial decrease in orthognathic activity (70 to 100% decrease in activity). At the time of completing the questionnaires for the report data censure, three hospitals still had not resumed operating for patients who required orthognathic surgery.

The treatment of maxillary or mandibular osteotomies was typically performed as inpatients (10/11 units). Patients undergoing bimaxillary osteotomies generally went to either a ward special (n=4) or a normal ward (n=7) postoperatively.

Non-melanoma skin cancers

Number of units which participated to QOMS: 7

Number of units which returned the organisational questionnaire: 10

50% (5/10) of participating units provide Mohs micrographic surgery as part of standard treatment for SCC/BCC and 7/10 offered a nurse-led wound care clinic to support patients post-operatively.

Summary

The mixed nature of the units participating in BAOMS QOMS ensures that the process and data collected represents the entire scope of practice (excluding Cleft Lip and Palate, and Craniofacial Surgery which have their respective established national audit/governance framework) and range of units. This reduces bias in the reporting of outcomes data and ensures that the findings published in this report are applicable and generalizable to the entire OMFS community in the UK. Most of the organisational data will be utilised by the project team to inform secondary analysis of the project outcomes data to support the caseload ascertainment process and enable comparative data trends between organisations of similar

levels of service provision. Variations in practice between OMFS units such as temporary tracheostomy rates and prophylactic antimicrobial therapy are useful observations which might influence the post-operative pathway of patients and in the latter area, might benefit from engagement in research/clinical trials such as the MANTRA NIHR trial ([Mandibular Trauma and Antibiotic Use](#)).

Some aspects of service variation such as the availability of expertise and resource for primary oral rehabilitation and anaesthetic input direct to the Head and Neck MDT set-up will require further evaluation as these are important aspects of the holistic care package which can have significant impact on patient experience and outcomes.

Oral and Dentoalveolar Surgery

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Analysis of Dentoalveolar referrals

Authors: Chiu G, Sassoon I, Puglia F and Ho M

Key points

- Almost 70% of patient referred to OMFS units for dentoalveolar problems are fit and healthy and most of them require relatively simple treatment
- Almost 85% of the referrals to OMFS units could have been managed in the community by the Tier 2 service (58.6%) or by primary care dentists (27.4%)
- Despite the triage of dentoalveolar referrals indicating that most of the patients referred could be managed in the primary care/community based specialist practices, all but one of these referrals were accepted for treatment in secondary care

Collaboration with the service commissioners, local dental committee and the managed clinical network teams will be essential to ensure that secondary care OMFS resources are optimally utilised in the management of oral and dentoalveolar pathology

Lay summary

Oral and Maxillofacial Surgery (OMFS) units across the UK receive a relatively large number of referrals from general dental practitioners and other dental specialties for conditions and/or problems related to their teeth, jaws and mouth. OMFS units based in hospitals are best equipped to treat patients with complex treatment needs i.e., complex medical history or treatment that requires complex surgery, also known as Tier 3 level of treatment patients. Approximately 70% of the referred patients are fit and well. Eighty-five percent of patients referred were assessed to have relatively simple treatment needs which could potentially have been managed in the general dental practice of specialist dental practices based in the community (Tiers 1 and 2 level of treatment patients). Despite this, OMFS units in hospitals have not felt able to divert these referrals to primary care and/or specialist dental practices in the community. In the context of sustained demand and pressure on NHS resources, OMFS units will need the collaborative support of the service commissioners, local dental committees and clinical networks to ensure that the treatment of patients within the appropriate settings can be achieved.

Introduction

The SSIG for dentoalveolar determined at the outset 2 projects that, whilst not strictly measuring outcomes, met a pressing need to report dentoalveolar activity in OMFS units, many of which are not affiliated with an undergraduate/post graduate dental school with onsite subspecialties of dentistry. The first project, ODA (Part 1) captures dental referrals and ODA (Part 2) records OMFS unscheduled (emergency) dentoalveolar workload to treat dentofacial or dentocervical infection.

A significant proportion of referrals to a secondary care OMFS unit are Oral and Dentoalveolar (ODA) pathologies. This group of referrals has contributed to increasing demands on hospital consultant service waiting lists since the dental contract reforms in 2006. (6)

[The recent Medical Education England Dental Programme Board Review of Oral Surgery Services and Training](#) recommended that much of the minor Oral Surgery care could be delivered by specialists in a Primary care setting. [Guide for Commissioning Oral Surgery and Oral Medicine Specialties](#) was published by NHS England in 2015. This resulted in development of the network of Providers who could provide an ODA Service in a Primary care setting. This was known as the “Tier 2” Service or “Intermediate Minor Oral Surgery”(IMOS) Service. Depending on the complexity of the procedure and the medical history of the patient a number of these referrals could be referred to these providers instead of to the secondary care. The aim was for the secondary care units to then receive the most complex of procedures and/or patients with a complex medical history, ensuring appropriate utilisation of NHS resources.

The levels of complexity are defined below and consider patients’ factors (medical history, social, patient anxiety and other patient-associated modifiers):

- **Tier 1** – Procedures/conditions to be performed or managed by a clinician commensurate with a level of competence as defined by the Curriculum for Dental Foundation Training or equivalent. This is the minimum that a commissioner would expect to be delivered in a primary care NHS Mandatory contract. Many dentists with experience have competencies above this
- **Tier 2** – defined as procedural and/or patient complexity requiring a clinician with enhanced skills and experience who may or may not be on a specialist register

- **Tier 3a** – Procedures/conditions to be performed or managed by a clinician recognised as a specialist at the General Dental Council (GDC) defined criteria and on a specialist list, OR by a consultant
- **Tier 3b** – Procedures/conditions to be performed or managed by a clinician recognised as a consultant in the relevant specialty, who has received additional training which enables them to deliver more complex care, lead multidisciplinary teams (MDTs), managed clinical networks (MCNs), and deliver specialist training. The consultant team may include trainees and/or staff and associate specialists (SAS) grades. Oral Surgery is to be delivered by Consultants in Oral & Maxillofacial Surgery who have the necessary competencies

Tier 1 and 2 procedures are usually performed in primary care settings. However, some Tier 1, 2 and 3 procedures may be performed in a secondary care setting if modifying patient factors or local circumstances require this e.g., requirement for skill mix and/or multidisciplinary team and/or general anaesthetic.

The aim of this part 1 ODA (ODA1) section for QOMS was to review the dentoalveolar referrals and evaluate the appropriateness of primary dental care referrals that are currently sent to secondary care OMFS units in England and Wales only. Part 2 (ODA2) is to report on the procedures performed and their appropriateness.

Due to the volume of referrals that OMFS units receive, this audit was open during predetermined windows of two-month period (Jan-Feb 2022) to ensure that the audit was feasible with the BAOMS QOMS data collection framework.

The QOMS ODA questionnaire included origin of the referrals, age, gender, reason for referral, relevant medical history, the tier attribution assigned by the secondary care OMFS clinician, and finally whether the referral was accepted or rejected. In this first year of data entry there were 449 entries registered into the BAOMS QOMS ODA1 REDCap registry.

Results

Origin of the referrals

The source of referrals to OMFS units in the ODA1 audit has been summarised in *Figure 4.1*.

Demographics

Patients' ages ranged from 6 months up to 95 years of

age (mean age = 46 years). The female to male ratio was 56%:43% (n= 254:196).

Figure 4.1

Reasons for referrals

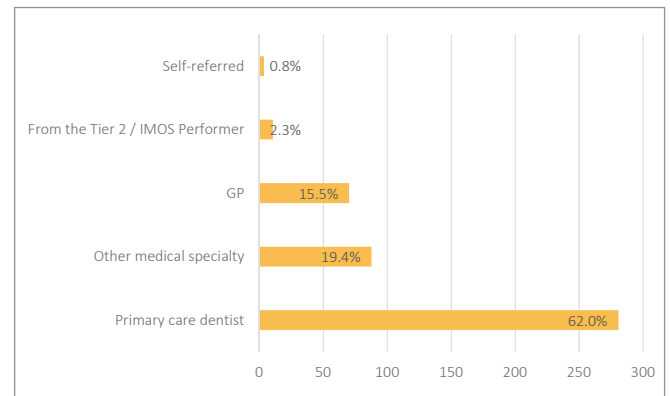
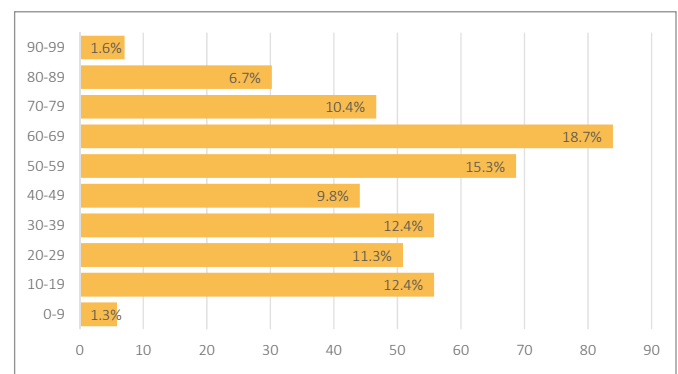


Figure 4.2

Age deciles distribution



Reasons for referral

The reasons for referral were classed into 11 groups (*Table 4.1 next page*).

Accompanying relevant medical history

In almost 70% of the referrals, patients had no relevant medical history as a need to warrant a referral to secondary care (*Table 4.2 next page*).

A further breakdown of the patients who had no relevant medical history is shown below (*Table 4.3 next page*).

Reasons for referrals of patients referred in ODA1

Table 4.1

Reasons for referrals	N (%)	Reasons for referrals	N (%)
Other Maxillofacial Issue	94 (20.1%)	Single Rooted Teeth	32 (7.1%)
Third Molars	85 (18.9%)	Polyps/Mucocele/Warts	30 (6.7%)
Simple Multiple Teeth	67 (14.9%)	Buried/Ectopic/Impacted/difficult teeth	28 (6.2%)
White patches/lichen Planus	49 (10.9%)	Other reasons for referrals *	13 (2.0%)

(* full dental clearances, deep roots and apicectomies)

Medical history of patients referred in ODA1

Table 4.2

Medical history	N (%)	Medical history	N (%)
None relevant	318 (69.1%)	On Bisphosphonates/Monoclonal Antibody medication	21 (4.6%)
On Anticoagulant Therapy	26 (5.65%)	Psychological Disorder	14 (3%)
Dental Anxiety	22 (4.8%)	Other relevant medical history *	38 (8.15%)
Diabetes	21 (4.6%)		

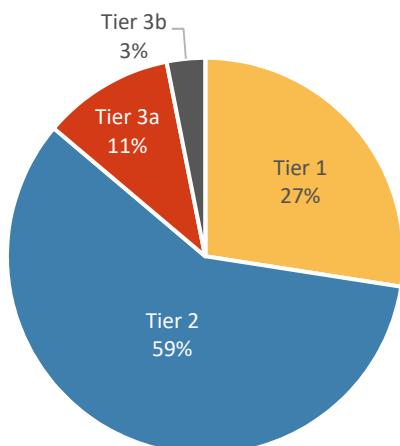
(*Previous radiotherapy, Bleeding disorder, Physical Disability affecting mobility, Immunocompromised, Psychiatric Disorder, on immunosuppression medication, Dementia with lack of competence, Learning difficulties and Movement disorder (e.g., Parkinson's))

Reasons for referrals of patients with no relevant medical history

Table 4.3

Reasons for referrals of patients	N (%)	Reasons for referrals of patients	N (%)
Third molars	65 (20.4%)	Buried/ectopic/impacted/ difficult teeth (non-3 rd molars or non-orthodontic)	19 (6.0%)
Orthodontic unerupted teeth for Exposures/Extraction	50 (15.7%)	Single rooted teeth/tooth	14 (4.4%)
White patch/Lichen planus	37 (11.6%)	Other reasons for referrals *	8 (2.5%)
Simple extraction of multiple teeth	28 (8.8%)	Other Maxillofacial issue	72 (22.6%)
Polyp/Mucocele/Warts	25 7.9%)		

(* full dental clearances, apicectomies and deep roots)



Tier attribution and triage outcome

This was based on evaluation of the referral by the secondary care clinicians (Figure 4.3). Almost 85% of the referrals were deemed to have been suitable for management in the community by the Tier 2 service (58.6%) or by their primary care dentist (27.4%). Despite this, all but one of the 449 referrals were accepted into the secondary care OMFS units (Figure 4.3).

Figure 4.3

Tier attribution of referrals

Summary

There was a significant number of patients with procedures (Tier 1 and Tier 2) appropriate for treatment in the community who were referred to secondary care. These would include single rooted teeth and simple extraction of multiple teeth. Apicectomies was the most infrequent cause of referral. Benign soft tissues (mucocoeles/polyps/warts) referrals were conditions that could potentially be managed in primary care provided that there was appropriate experienced clinicians working within the governance framework of a managed clinical network with secondary care consultation and/or oversight, with the collaborative support of pathology reporting services with clear and detailed alert systems in place for any unexpected

diagnosis of malignancy brought to the attention of the relevant Head and Neck multidisciplinary teams.

There is perhaps sufficient information gathered in this data collection cycle to support the need for OMFS units involved to review the service provision in their catchment areas with the commissioners and local dental committees. The main weakness of the ODA1 audit was the number of units contributing to the dataset is relatively small within the context of OMFS units providing ODA services in the UK, however as the selection of BAOMS funded units for data co-ordinator support was through an objective and stringent process, the project committee feels confident that the findings from this year's data collection would provide a reasonable representation of the national scene.

Incidence of oro-cervical infections from an odontogenic origin

Authors: Chiu G, Sassoon I, Puglia F and Ho M

Key points

- Over 75% of patients who present with oro-cervical infection present with pain and/or oro-cervical swelling
- A significant proportion of patients present with acute exacerbation of their existing chronic dentoalveolar pathology (e.g., caries and/or chronic infection), whilst some present after they have developed complications following treatment in primary care
- More than 60% of patients require dental extraction and/or drainage of oro-cervical infection under general anaesthesia. Most of these patients receive care on a surgical ward after treatment
- Just under 60% of patients require surgical intervention within 24 hours of treatment
- Data completion and further refinement of the dataset for this audit are areas which requires further feedback and improvement within the QOMS project team

Lay summary

OMFS units provide acute and urgent care for patients who present with infections in the mouth which can spread to involve neck spaces. These infections can require complex treatment, care and occasionally be life threatening. Over 75% of patient who present with infection in the mouth and neck experience severe dental pain and/or mouth/neck swelling, which can be distressing for patients and their relatives. Patient presenting to OMFS units with these problems are generally due to decayed teeth, some of which have developed swelling and/or abscesses. A significant proportion of patients present with infection following treatment they have received with their dentists. The commonest treatment required is extraction of teeth with/without surgical drainage of neck swellings (pus collection). Over 60% of patient who present require treatment within 24 hours of attendance to hospitals. Just under 60% of these patients required general anaesthesia for treatment. The difficulty in accessing appropriate care by a dentist can have significant health and economic impact on patients and the NHS. Planning for appropriate provision of oral health care in the community has the potential to improve the utilisation of resources in the NHS and hospitals.

Introduction

There has been a reduction in access to dental practices in recent years which has been exacerbated by the impact of the COVID-19 pandemic. Waiting times for dental extraction has significantly increased. This may have resulted in an increased number of patients developing acute infections on chronic conditions associated with their carious/diseased dentition.

The aim of this part of the QOMS project is to look at the epidemiology of the patients seen in secondary care OMFS units with oro-cervical infections.

Results

199 entries were made into REDCap between the months of January and February 2022. Seven hospitals participated in this audit.

Demographics

The most frequent presentation occurred in the age category between 20-30 years of age (N = 47, 27%). There is clear reduction in the numbers as the age categories increase (Figure 4.4). There was a 50:50 split between male (n=96) and female (n=96), although 5 patients were not assigned a gender category. Most of the patients that had been entered appeared to be relatively well with little in the way of co-morbidities that have been listed (Tables 4.4 and 4.5).

The most common pathologies causing the infection were caries from multiple teeth (28.5%) and caries from multiple teeth (28%) (Figure 4.5). There were a number of entries n=36 (19%) where patients have had previous procedures and presented with complications (e.g., post dental extraction infection, dry socket, previous coronectomy and oroantral fistula).

Presentation of infection

Most patients presented with swelling and/or dental pain (n=145, 38.7%), followed by trismus (n=142, 37.9%) (Table 4.6). The origin of dentoalveolar infection has been summarised in Figure 4.7. Patients with lower teeth infection were most likely to present to secondary care units. There was a proportion of patients for whom this information was reported as "not applicable" or "not in the notes" (n=26, 12.8%).

Of patients who had a previous treatment prior to their index presentation to OMFS units (n=41, 20.6%), the presenting

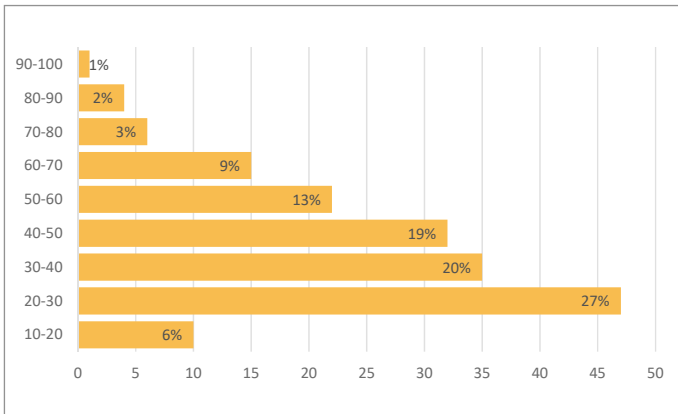


Figure 4.4

Age deciles of patients seen in QOMS OMFS units with oro-cervical infection

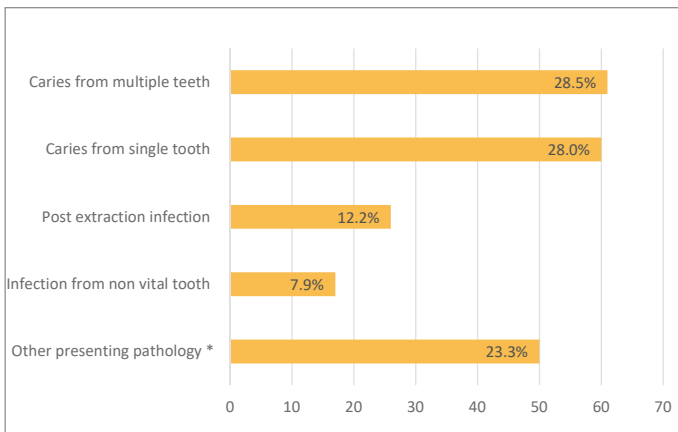


Figure 4.5

Cause of oro-cervical infection of patients who presented to the QOMS maxillofacial units

(* Caries to third molar only, pericoronitis from third molar, Infected cyst, retained root left in situ, Periodontal disease, Dry socket, Previous coronectomy, Oral cutaneous fistula, Oral antral fistula, other reasons not listed)

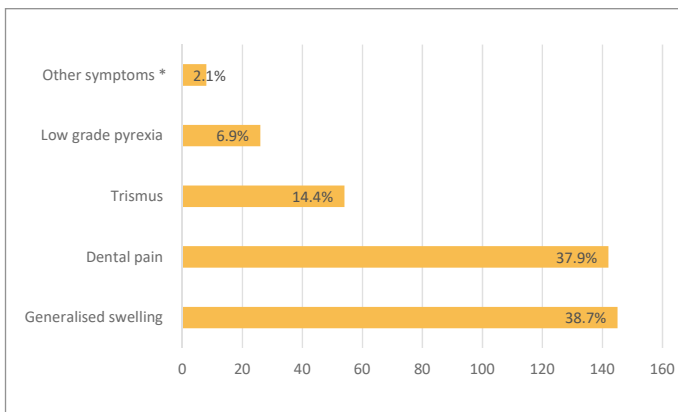


Figure 4.6

Presenting symptoms of patients who attended the QOMS maxillofacial units

(* Sepsis, Sinusitis, Skin sinus)

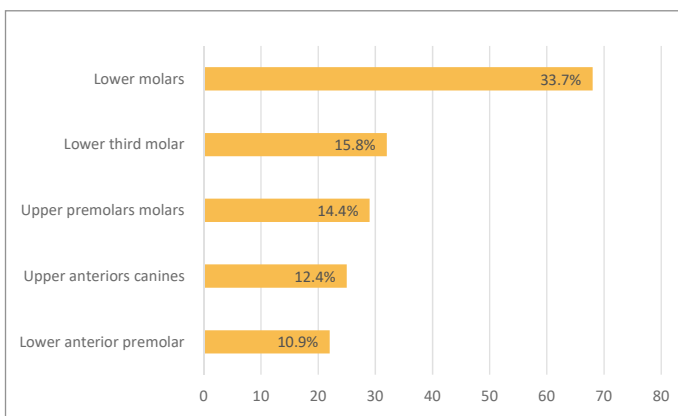


Figure 4.7

Origin of oro-cervical of patients who attended the QOMS maxillofacial units

Smoking status of patients seen in QOMS OMFS units with oro-cervical infection

Table 4.4

Smoking status	N (%)	Smoking status	N (%)
Never smoked	82 (41.6%)	Ex-smoker	7 (3.5%)
Current smoker	45 (22.8%)	Declined/not reported	57 (28.9%)

Medical history/comorbidities of patients who presented with oro-cervical infection

Table 4.5

Comorbidities	N (%)	Comorbidities	N (%)
None listed below	134 (83.2%)	Diabetes	6 (3.7%)
Severe anxiety	7 (4.3%)	Other medical history / co-morbidity *	14 (8.7%)

(* Severe anxiety, Diabetes, Dementia/Lack of Competence, On Anticoagulants, Psychiatric Disorder, Previous radiotherapy, Immunocompromised, Bleeding disorder, Movement Disorder, On Bisphosphonates)

Treatment provided for patients who presented with oro-cervical infection to QOMS oral and maxillofacial surgery units

Table 4.6

Treatment	N (%)	Treatment	N (%)
Extractions of teeth	102 (26.8%)	Oral antibiotics	49 (12.9%)
Intra oral incision and drainage	83 (21.8%)	Extra oral incision and drainage	32 (8.4%)
Intravenous (IV) antibiotics	76 (20.0%)	Wash out and debridement of socket	25 (6.6%)
Other *	14 (3.7%)		

(* Reassurance, removal of root tip or fragment, packing of socket, alvogyll, Removal of bone fragments, Haemostatic measures, tracheostomy)

Type of anaesthesia for patients who presented with oro-cervical infection to QOMS oral and maxillofacial surgery unit

Table 4.7

Type of anaesthesia	N (%)	Type of anaesthesia	N (%)
General Anaesthetic (GA) with standard intubation	85 (43.2%)	General Anaesthetic with awake fibre optic intubation	28 (14.2%)
Local Anaesthetic	45 (22.8%)	Local Anaesthetic with IV sedation	3 (1.5%)
None	31 (15.7%)		

NCEPOD category patients who presented with oro-cervical infection to QOMS oral and maxillofacial surgery units

Table 4.8

NCEPOD category	N (%)	NCEPOD category	N (%)
1 - Immediate	8 (4.0%)	3 - Within days	17 (8.6%)
2a - Within 6 hours	22 (11.0%)	Elective treatment	40 (20.3%)
2b - Within 24 hours	90 (45.7%)		

Level of hospital care and discharge destination of patients who presented with oro-cervical infection to QOMS oral and maxillofacial surgery units

Table 4.9

Level of hospital care	N (%)	Discharge/follow-up	N (%)
Admitted to a hospital ward	35 (17.8%)	Discharged with follow up	31 (15.7%)
Admitted to ITU/High Dependency	1 (0.5%)	Discharged with no follow up	111 (56.4%)

infections were complications of their treatment, and previous dental extraction was the most common treatment associated with their dentoalveolar infection (n=26, 63.4%). Other previous treatments included placement of implants, coronectomy, root canal treatment and dental restoration.

The treatment provided for patients in this audit has been summarised in *Table 4.6*. Most patients required a procedure to extract carious teeth and/or a form of surgical drainage was required. None of the patients in this audit required a tracheostomy.

The type of anaesthesia utilised for patients (when indicated) has been summarised in *Table 4.7* (no information was available for five records, 2.5%). Fifty of the patients that needed a GA were due to the infection which had arisen from the lower molars (n=37) or the lower 3rd molars (n=13). Over half of patients who presented with infections required GA. Nineteen patients that needed an awake fibre optic intubation were either from third molars (n=11) or lower molars (n=8).

The NCEPOD Classification of Intervention for patients in this audit have been summarised in *Table 4.8*. Fifteen percent of patients who presented required surgical intervention within 6 hours of presentation and an additional 46% required intervention within 24 hours. It was not documented for 19 records (9.6%).

Discussion and Summary

Patients presenting with an oro-cervical/facial infection from a dentoalveolar cause contribute to a significant workload in secondary care OMFS units, especially in the acute setting. Most of the patients in this data set were fit and well. A significant proportion of patients recently had an intervention prior to presenting with an infection. Most of these were from previous dental extractions. Several patients needed urgent surgical intervention including awake fibre optic intubation. Factors such as access to primary care dentistry: timeliness of attendance and/or intervention, accuracy of diagnosis and efficacy of treatment received could all contribute to the need to receive further intervention.

A considerable number of patients in the audit did not have smoking status assigned with the registry. It may

be that the entries are entered retrospectively, as result the smoking status of the patient has not been found in the notes. Local clinical leadership, departmental commitment to the QOMS initiative and data co-ordinator training/support are perhaps deficient in units where this information has not frequently been collected. This will require feedback, education and follow-up to emphasise the importance of accurate and complete data collection. The project team will further review the level of details required within the audit to ensure that they remain clinically relevant and feasible to collect.

Strategies to reduce infection after dental extractions should be considered. Use of antimicrobial therapy appropriately, surgical technique and wound care are some factors to consider. The persistent challenges patients face in accessing dentists will inevitably continue to contribute to presentation to secondary care with oro-cervical/facial infection from a dentoalveolar cause. This data is important as it can only highlight to the health policy makers and commissioners' implications of the current level of services available in primary dental care on the secondary care in the NHS. There are significant health-economic implications as treatment in secondary care is more costly, especially if advanced surgical, anaesthetic and nursing care is required. In complex and/or late presenting acute infection, patients can require escalation of the level of hospital care to HDU/ITU care. Furthermore, treatment in secondary care often results in more time off from employment and/or education, adding to the economic burden for patients and the social/healthcare services.

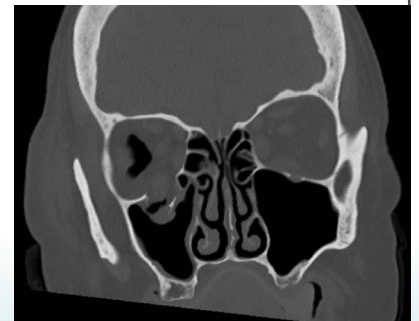
Recommendations

This section of QOMS will be refined and more OMFS units should be encouraged to participate to provide a wider picture to account for regional variations and compare the outcomes in the 4 nations who have some differences in their provision of primary dental care.

Further development of the questionnaire to more accurately details the nature and complexity of interventions required in secondary care will allow more accurate assessment of the true impact this group of patients can have in the delivery of OMFS services.

Oral and maxillofacial trauma

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Authors: Chiu G, Sassoon I, Puglia F and Ho M

The management of Oral and Maxillofacial Trauma forms a significant component of the acute workload within the specialty. In identifying the areas of clinical practice which were suitable for inclusion for the QOMS initiative, the BAOMS Trauma SSIG was consulted. Management of mandibular and isolated orbital wall fractures (not including orbito-zygomatic injuries) were identified as conditions and procedures with clear identifiable outcomes suitable for measurement in clinical practice which would be good indicators of the quality of treatment provided for the management of maxillofacial trauma in each OMFS units.

The common metrics selected for both types of fractures were unplanned return to theatre and readmissions within 30 days from surgery. Visual problems and enophthalmos were additional indicators selected for the management of isolated orbital wall fractures.

Key points

- In the management of mandibular fractures (664 patients), the returns to theatre rate was low (1.2%) with an even lower unplanned readmission rate
- In patients treated for orbital floor/wall fractures surgery (108 patients), 3% developed complications prior to hospital discharge and 6% required readmission within 90 days of. Three percent of patients developed post-operative visual problems or diplopia within 90 days of surgery.
- Patients underwent pre-treatment cross sectional imaging (n=70/109, 64.2%) and ophthalmology assessment (n=61/109, 56.0%). Pre-treatment assessment and evaluation of orbital floor/wall fractures will require further investigation to ascertain whether the data presented represents genuine variation in practice (potential scope for education and training) or scope for improvement in data collection in QOMS OMFS units
- The dataset could perhaps be further refined to ensure that it remains simple and as accurate as possible in providing information to measure the clinically relevant metrics for QOMS which may benefit from reappraisal in view of the emergence of NCIP for OMFS

Lay summary

Fractures of the lower jaw and walls of the eye socket are facial injuries which are treated regularly in Oral and Maxillofacial

Surgery departments. Most of these injuries occur due to interpersonal violence and if not treated appropriately, they might cause significant disability to patients. The treatment of lower jaw fractures observed in this report have generally been successful with very low complication rates (1.2%). A very small proportion of patient treated for eye socket wall fractures developed complications before discharge (3%) and 6% of these patients had to be readmitted for hospital with complications within 90 days of their operations. Three percent of patients developed double vision or problems with their vision within this period of time. Just over one-fifth of patient treated did not have a scan of their eye socket or an eye specialist assessment which are important baseline evaluations before treatment for these injuries. The information obtained from this period of data collection will be fed back to Oral and Maxillofacial Surgery departments for the next phase of service quality improvement.

Mandibular Fractures

Introduction

Mandibular fractures are one of the most common types of facial fractures that present to an OMFS unit. The Trauma database has been open since June 1st, 2021.

The first section of this chapter will describe the treatment related activities and outcomes in the management of mandibular fractures. Data was collected for the following fields:

- Patient demography
- Clinical presentation details and risk factors
- Details of fractures and management
- Early post-treatment complications
- Readmission/complications at 90 days after treatment

Results

Demographics

There were 664 entries made, with most of the patients presenting in the 20–30 age category (n=216, 38.3%). (Figure 5.1) There were significantly more men (n=530, 79.8%) presented than females (n=86, 12.9%). There 47 (7%) entries with no gender assignment. Most were patients had no known medical comorbidities (n=542, 79.9%), and the details of medical risk factors for patients have been summarised in Table 5.1.

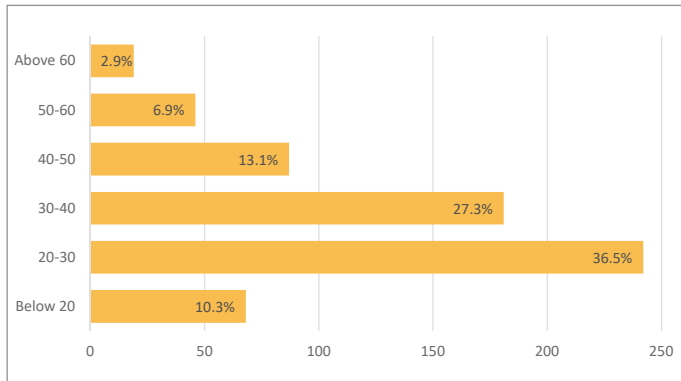


Figure 5.1

Age of patients at presentation/ treatment for mandibular fractures in the QOMS dataset

Comorbidities	N (%)	Comorbidities	N (%)
None known	542 (79.9%)	Psychiatric Disorder	27 (3.9%)
Alcohol Excess	45 (6.6%)	Other risk factors *	22 (3.15%)
Psychological Disorder	41 (6.0%)		

Table 5.1

Medical Risk Factors of QOMS mandibular fracture patients in the dataset

(*Diabetes, On anticoagulants, On bisphosphonates, Bleeding disorder, Dementia, Immunocompromised, On immunosuppression medication, Previous Radiotherapy, Movement disorder, Physical Disability)

Presentation

Most mandibular fractures occurred in isolation (n=528, 79.6%). Concomitant soft tissue lacerations were the most common other injury (n=67, 10%). In the reported cohort of patients there we no associated neck injury

or skull fracture (Figure 5.2). Interpersonal violence with bodily contact was the most common cause of sustaining a mandibular fracture (n=436, 65.6%). The next most common cause was a mechanical fall (n=74, 11.1%) followed closely by sporting injuries (n=66, 9.9%) (Table 5.2).

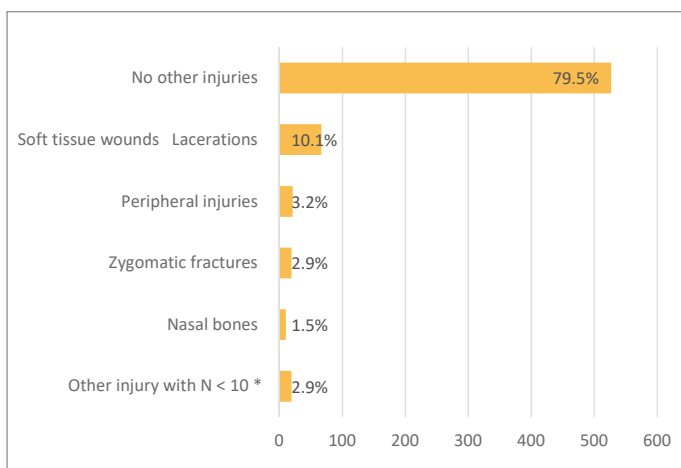


Figure 5.2

Concomitant injuries in patients who presented with mandibular fractures in the QOMS dataset

(* LeFort 1, LeFort 2, Head injury, LeFort 3, Skull fracture, Neck injuries, Blindness)

Aetiology	N (%)	Aetiology	N (%)
Alleged assault with fist/feet	436 (65.6%)	Alleged assault with object/weapon	20 (3.0%)
Mechanical fall	74 (11.1%)	Non-mechanical fall	15 (2.2%)
Sports / Exercise / Accidental injury	66 (9.9%)	Other aetiologies *	6 (0.9%)
Road traffic accident	33 (4.9%)	Not documented	12 (1.8%)

Table 5.2

Summary of the aetiology of mandibular fractures in the QOMS dataset

(* Industrial injury, Self-harm / suicide attempt)

Site, extent, and types of mandibular fractures in patients who presented to OMFS units who participated in this cycle of the QOMS data entry

Table 5.3

Fracture location	Comminuted N (%)	Simple N (%)	Un-displaced N (%)
Ramus	5 (4%)	13 (2%)	11 (6%)
Symphysis	4 (3%)	32 (4%)	11 (6%)
Parasymphysis	35 (29%)	215 (30%)	58 (31%)
Body	16 (13%)	63 (9%)	15 (8%)
Angle	39 (32%)	257 (36%)	55 (29%)
Subcondylar	16 (13%)	119 (17%)	30 (16%)
Intra Capsular	6 (5%)	17 (2%)	9 (5%)
Total	121	716	189

Treatment vs fracture location

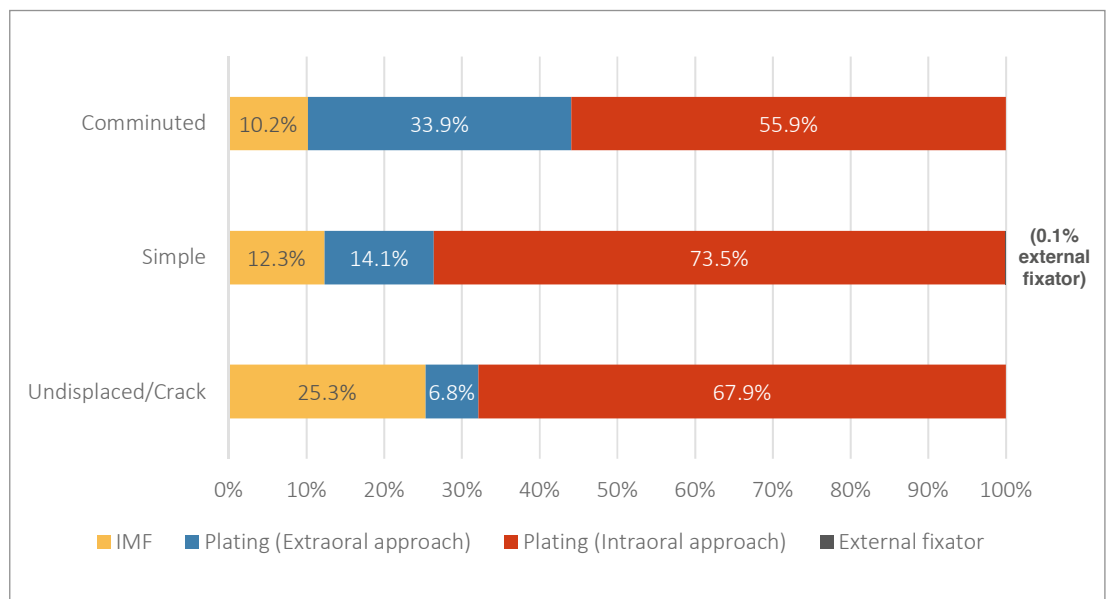
Table 5.4

Fracture location	IMF N (%)	Extraoral Plate N (%)	Intraoral Plate N (%)
Ramus	10 (7%)	6 (4%)	13 (2%)
Symphysis	4 (3%)	3 (2%)	38 (6%)
Parasymphysis*	34 (24%)	7 (5%)	264 (39%)
Body	3 (2%)	12 (8%)	74 (11%)
Angle	19 (14%)	58 (39%)	261 (38%)
Subcondylar	55 (39%)	61 (41%)	27 (4%)
Intra Capsular	15 (11%)	3 (2%)	3 (0%)
Total	140	150	680

(* One patient required external fixator)

Treatment by type of fracture

Figure 5.3



Eight patients (1.2%) required return to theatre during their acute admission. The reasons were mal-occlusion (n = 3), inadequate fracture reduction (n = 2) and infection (n = 1). In the remaining 2 patients, the cause for further surgical intervention were for bicoronal flap, treatment of mid face fractures and arch bars, and evacuation of haematoma/sialoceles right mandibular condyle incision site.

The median length of stay in hospital was 1 day (range 0-373). The grade of operating surgeon within the patient cohort is summarised in *Table 5.5*.

Summary

Most of the fractures occurred in the 20-30 age group who were generally fit and well men. Injuries were mainly the result of interpersonal violence and isolated to the mandible. Most fractures occurred at the angle or parasymphiseal region

and were treated with intra oral plates. The complication rates reported were low.

The details of complications/readmission at 90 days were relatively sparse, this could reflect the relatively low complication rates or perhaps the need for local data coordinators to ensure that readmission data is completed contemporaneously with the support of the clinical teams. This data field is currently recorded in the Hospital Episode Statistics dataset which is accessible through the NCIP portal.

The dataset collected has provided the basis for development of risk adjustment in mandibular trauma treatment. The dataset could perhaps be simplified to ensure that it remains simple and as accurate as possible in providing information to measure the clinically relevant metrics for QOMS which may benefit from reappraisal in view of the emergence of NCIP for OMFS.

Grade of operating surgeon for patients with mandibular fractures in the QOMS dataset

Table 5.5

Grade of operating surgeon	N (%)	Grade of operating surgeon	N (%)
Consultant	341 (41.6%)	Dental core trainee	14 (1.7%)
Specialist registrar	326 (39.8%)	Locum consultant	3 (0.4%)
Dentally qualified medical student	57 (7.0%)	Medically qualified dental student	0 (0.0%)
Associate specialist	55 (6.7%)		

Orbital floor/wall Fractures

Introduction

Isolated orbital floor and/or wall fractures were the other aspect of OMFS trauma evaluated as it is relatively low volume, when compared to e.g., orbito-zygomatic complex fractures, and is an area of OMFS trauma practice with high stakes complications such as visual problems or even visual loss, which can have significant impact on patients' lives especially if they are in active employment/education.

Results

Demographic and presentation

Between June 1st, 2021, and June 30th, 2022, one hundred and eight patients were entered into the database, of which 76 patients were male and 32 patients were female. The majority of the injuries occurred between the ages of 20 to 50 years. Most of the patients were fit and well with no medical issues (n=93; 87%). Most of the orbital floor injuries were because of interpersonal violence (*Table 5.6*).

Mechanism of Injury of patients who presented with orbital floor /wall fractures in QOMS participating OMFS units

Table 5.6

Aetiology	N (%)
Alleged assault with fist/feet	58 (53.2%)
Sports / Exercise / Accidental injury	21 (19.3%)
Mechanical fall	15 (13.8%)
Other mechanisms of injury *	15 (13.8%)

(* Road traffic accident, non-mechanical fall, alleged assault with object/weapon, industrial injury, self-harm / suicide attempt)

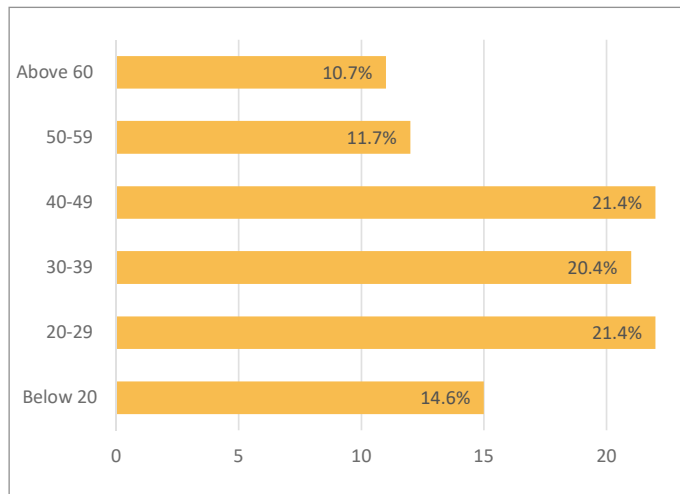


Figure 5.4

Age profile of patients who presented with orbital floor/wall fractures in QOMS participating OMFS units

Pre-operative investigations

Seventy patients (65%) had a CT scan prior to their operation. Ten (9%) patients did not have any cross-sectional imaging prior to treatment.

Sixty-one patients (57%) had been reviewed by the ophthalmology team, whereas 18 (16%) patients were not assessed by the ophthalmology team prior to treatment. There was no documented data entry for whether patients had pre-treatment cross sectional imaging and ophthalmology assessment for 24 patients.

Timing of operation

The median time from injury to surgery was 15 days (0-987). The median time from having their pre-operative investigation to their operation was 8 days.

Fracture location and treatment

Details of the location of the orbital injuries, types of implant utilised for fracture repair / reconstruction, surgical approach and grade of operating surgeons have been summarized in Tables 5.7 to 5.10.

Complications

Four (3%) patients developed complications before discharge that required return to theatre. The reported

issues were persistent double vision, drainage of a retrobulbar haemorrhage, removal of implant prosthesis, and a divergent squint after the first operation.

Re-admission after 90 days (Total number of entries =88)
Five patients (6%) required re-admission within 90 days from surgery to repair their orbital floor/wall fractures. Two patients required to return to theatre (muscle entrapment and re-repair). Other complications included persistent diplopia (n=2), reduced visual acuity (n=1) and infection from the implant (n=1).

Summary

Most of the orbital injuries that present to QOMS participating OMFS units were caused by interpersonal violence in patients who are relatively fit and well. The median time of operation from injury occurring was 15 days. The variation in practice with regard to preoperative investigations and assessment i.e., CT orbits and ophthalmology assessment requires further interrogation and will be an area of practice that will receive more attention in the QOMS participating units. The access to the fracture was mainly performed by a subconjunctival approach. The recorded complications were low overall. Due to the relatively early phase of data collection, late complications/visual problems data is awaited, and the future report will provide a more complete overview of the management of orbital floor/wall injuries in QOMS active OMFS units.

Orbital fracture location of patients who presented with orbital floor/wall fractures in QOMS participating OMFS units

Table 5.

Fracture site	N (%)
Isolated floor	67 (61.5%)
Floor and medial wall	34 (31.2%)
Isolated medial wall	6 (5.5%)

Material used to repair orbital floor/wall defects of patients who presented with orbital floor/wall fractures in QOMS participating OMFS units

Table 5.8

Materials used to repair orbital fractures	N (%)
Titanium pre-formed	44 (43.1%)
Titanium Sheet	20 (19.6%)
No Treatment	18 (17.6%)
PDS Sheet	12 (11.8%)
Other materials used for repair *	8 (7.8%)

(* Autologous Bone, PEEK patient specific implant, Medpor sheet)

Surgical access of patients who presented with orbital floor/wall fractures in QOMS participating OMFS units

Table 5.9

Surgical access	N (%)
Subconjunctival	69 (63.3%)
Sub ciliary	13 (11.9%)
Infra orbital crease	11 (10.1%)

Grade of Surgeon performing the procedure of patients who presented with orbital floor/wall fractures in QOMS participating OMFS units

Table 5.10

Grade of Surgeon	N (%)
Consultant	91 (75.8%)
Specialist registrar	25 (20.8%)
Other surgical grades *	4 (3.3%)

(* Associate specialist, Dental core trainee, No Documented)

Orthognathic surgery

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Authors: Ayoub A, Sassoon I, Puglia F and Ho M

Summary

Overall treatment of patients with dentofacial deformity in the QOMS OMFS units had very low early complication rates – 2% return to theatre within 30 days (124 patients in total from 9 OMFS units). Median length of hospital stay was 1 day. The number of patient cases reported in the series has been lower than expected due to the impact of COVID-19 on multiple OMFS units. At the time of writing, the provision Orthognathic Surgery has just been restarted after a significant period of pause in most OMFS units across the UK (accepting there will have been regional variations).

Lay summary

The surgical treatment of patients with dental and facial deformities has been interrupted significantly due to the COVID-19 pandemic. The activities recorded within this cycle of data collection is therefore not representative of the normal number of patients who would have had treatment for these conditions. The treatment complication rates reported have been low and most patient stayed one day in hospital after orthognathic surgery procedures in general. The record of activities within this subspecialist area of Oral and Maxillofacial Surgery is still at an early stage when compared to the other sections of this report.

Introduction

The orthognathic surgery registry was redesigned by the current Orthognathic Surgery subgroup of the QOMS project, work began in summer 2020 and the current version of the registry was open for data collection in August 2021. A previous iteration was tested in the first feasibility pilot phase around the end of 2019 and based on the feedback received the current registry was developed. The Orthognathic SSIG had decided at the beginning of the BAOMS QOMS initiative in 2018 that the procedures that will be evaluated by the project would be LeFort I and mandibular bilateral sagittal split osteotomies and the quality-of-care indicators to be measured would be unplanned returns to theatre, unplanned readmissions following discharge from hospital and postoperative hospital length of stay.

Results

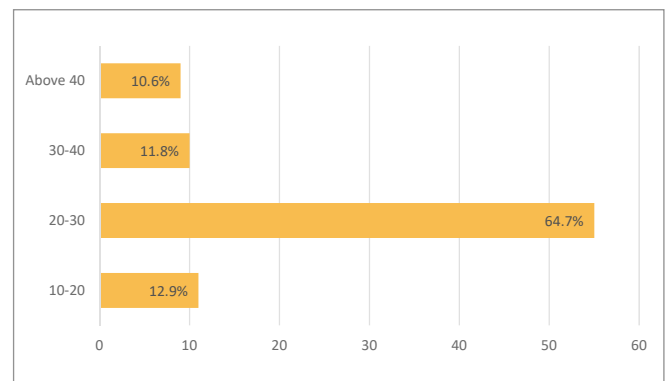
The following report is based on data contributed on 170 returns from 9 OMFS units. One of the participating units was however excluded due their high rate of missing data (n=46). The final sample used for analysis included 124 records.

Demography

The mean age of 65% of the patients was 27 years, ranging from 19 to 60 years of age. Most of the patients were of an age between 20-30 years (*Figure 6.1*). Age was missing for 39 patients (31.5%). Females constituted 58% of the complete submitted records (39 patients were missing gender)

Figure 6.1

Age decile distribution



The main indication for orthognathic surgery was the correction of dentofacial dysmorphology (n=75, 69%) while dysfunction (chewing and biting) was reported in 34 (31%) cases.

Diagnosis: technology modalities utilised and patient presentation

Standard 2D photographs and dental study models were the main diagnostic aids used in most of the patient cases. Novel application of intraoral scanning and the 3D stereophotogrammetry were utilised in 3% and 2% of the orthognathic patients, respectively. Lateral cephalographs and OPT were the main radiographs used for the diagnosis and management of dentofacial deformities in 75% of the maxillofacial units. Cone beam (CB) CT scans or conventional CT scans were used for the analysis and the planning of the remaining patients.

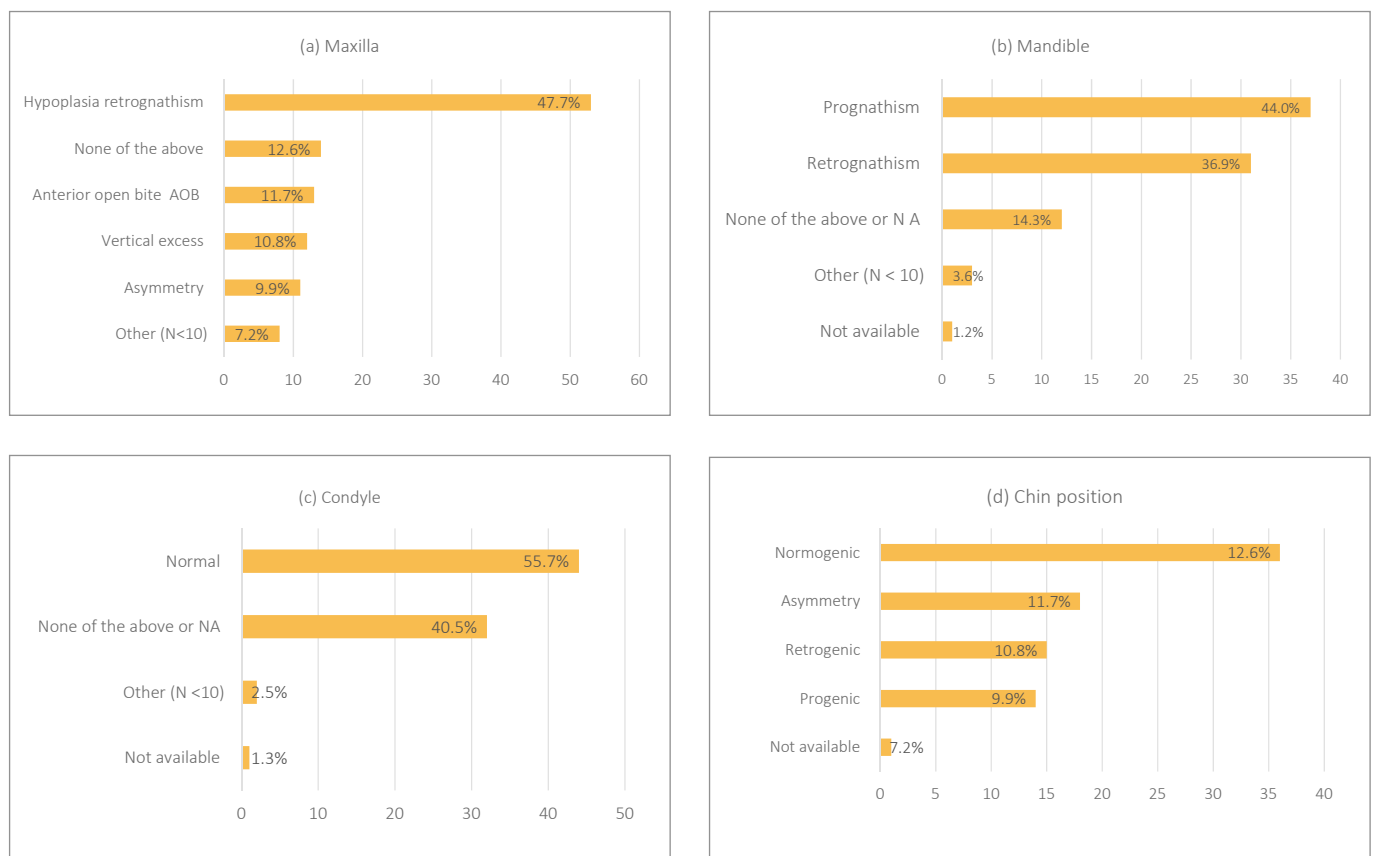
The most common type of the dentofacial deformities (n=53, 47.7%) of the mid face, which required orthognathic surgical correction was antero-posterior maxillary hypoplasia, followed by anterior open bite in 12% of the

patients. Vertical maxillary excess was the main indication for surgery in 10.8% (n=12) of the cases, asymmetry was the other frequent diagnosis in 9.9% (n=11) of the cases which required orthognathic surgical correction. Mandibular prognathism was the most common lower face deformity which was noted in 44.0% (n=37) of the

patients followed by mandibular retrognathism in 36.9% (n=31). Correction of mandibular asymmetry was required in about 4% of the patients. Therefore, Le Fort I maxillary osteotomy and sagittal split osteotomy were the two most common surgical procedure carried out (n=63, 45% and n=69, 48%, respectively) (Figures 6.2(a)-(d)).

Figures 6.2

Reported deformities of the maxilla (a), mandible (b), condyle (c) and the position of the chin (d)



The 3rd molar was removed in 17.7% (n=22) of the patient cases during surgery and in 16.9% (n=21) of them following surgery. In majority of the patients (n=37, 30%) the 3rd molar was not removed. The mandibular body osteotomy was performed in 1% of patients. Simultaneous Iliac crest bone graft was required in 1.4% of patients.

In most of the patients the condylar process appeared normal (n=44, 55.7%), in 3% of the submitted patient records, condylar hyperplasia or atrophy were diagnosed before surgery. Normal chin prominence was recorded in 42.9% (n=36) of the patients, retrogenia was identified in

17.9% (n=15) of the cases and progenia in 16.7% (n=14). Chin asymmetry was the most common deformity of the chin which was detected in 21% (n=18) of the patients. Limited number of simultaneous genioplasty was carried out, in 3% of the patients.

The Index of Functional Orthognathic Treatment Need (IOFTN) (7) provides an overall grading of the severity of the functional disorder secondary to the dentofacial deformity. In 62% (n=77) of the patients the IOFTN was above 4 which confirms and justifies the high need for orthognathic surgery.

Multidisciplinary management

In most of the patients (n=61, 49.2%) both pre-surgical and postsurgical orthodontic treatments were applied to maximize occlusal contact. Pre-surgical orthodontic treatment for dental decompensation was only considered in 11.3% (n=14) of the cases. The average duration of the orthodontic treatment was about three years (missing data in 50% of the patients which could include patients who did not have any orthodontic treatment). The average interval between the start of the treatment to the date of surgery was one year, this included the time required for pre-surgical orthodontic treatment.

Prediction planning

Prediction planning was considered by all orthognathic teams for all the patients treated, it was limited to the standard model surgery in 35.5% (n=33) of the patients and to 2D digital planning in 16.1% (n=15). The 3D virtual planning was carried out for 48.4% (n=45) of the patients. The majority of these patients (n=45, 53.6%) had the occlusal wafer printed to guide the surgical movements of the osteotomy segments. Printed 3D laser sintered plate was utilised in 7% (n=6) of patients. Surgical guides were not used in 1% (n=1) of the patients.

Most of the patients stayed one day in the hospital following surgery.

Complications

The majority of the patients (n = 70, 90%) did not experience any intraoperative surgical complications. Most of the reported complications were associated with sagittal split mandibular osteotomy (n = 7, 9%). Unfavourable mandibular split was reported in three patients, one patient had an unfavourable downfracture of the maxilla and the transection of the inferior alveolar nerve was noted in 4 patients.

No postoperative complications were detected in most of the patients (n= 77, 96%). Bleeding was reported in

one patient, one patient developed deviation of the nasal septum and one patient developed an infection.

Return to theatre within 30 days

Three patients required further surgery one to deal with nasal septal deviation, the second to control bleeding and the third to deal with infection.

The dataset was not mature enough to report on readmissions within 90 days post-surgery.

Summary

Overall treatment of patients with dentofacial deformity in the QOMS OMFS units had very low early complication rates. The number of patient cases reported in the series has been lower than expected due to the impact of COVID-19 on multiple OMFS units, at the time of writing, the provision Orthognathic Surgery has just been restarted after a significant period of pause. The multidisciplinary nature of orthognathic treatment and long duration of treatment and follow-up can make complete data collection challenging especially when input from orthodontic colleagues is required. It is hoped that following extensive collaborative consultation between the BAOMS QOMS Orthognathic Surgery representative and the British Orthodontic Society representatives to develop the Orthognathic Surgery Patient-Reported Outcomes Measures (PROMs) questionnaire, we will be successful in improving multidisciplinary data contribution to this subgroup of patients. The PROMs which have been developed will form an important component of the evaluation of the value and impact of orthognathic surgery for our patients, which will hopefully provide clear reported data of the patient perceived benefits of orthognathic surgery and the impact the treatment provided have on their lives. The combined factors of increased surgical throughput as the NHS recovers elective surgical activity and the increasing number of patients registered into the audit with more mature data will hopefully provide a larger and more detailed dataset to test the metrics selected to measure performance of OMFS units in the next report.

Non-melanoma skin cancers

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Authors: Kyzas P, Tighe D, Sassoon I, Puglia F and Ho M

Key points

- Dermoscopy underutilised amongst OMFS clinicians treating skin cancers; preoperative biopsies taken in 1/3 of the patients included in this report
- High incidence of incomplete excisions for cutaneous SCCs
- Clinical T stage for SCC and predetermined margins under-reported – potential need to revisit the fundamentals of skin cancer staging and its implications on treatment and outcome

Lay summary

The main types of skin cancer include melanoma (which is the most aggressive but rarest), basal cell carcinoma - BCC (the commonest and the most innocent) and squamous cell carcinoma - SCC (aggressive and the less common compared to BCC). SCC and BCC are collectively called Non-Melanoma Skin Cancers (NMSC); a term coined to indicate their different treatment approach and prognosis compared to melanoma. SCCs are more aggressive than BCCs, as they can spread to the lymph glands of the neck. Treatment for NMSC is usually surgery. Surgeons remove these lesions allowing for an additional margin of healthy-looking skin around the lesion (this is called predetermined margin), to ensure that all the cancer is removed at a microscopic level. These lesions can be diagnosed before treatment with the aid of a technique called dermoscopy. This is essentially the use of a specially designed magnifying glass that highlights specific clinical features of the lesions, allowing clinicians to diagnose these without the need of a biopsy. Biopsies before definitive treatment can delay surgery and incur cost to the NHS.

The Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) initiative is a Quality Improvement project within the specialty of Oral & Maxillofacial Surgery (OMFS). The project spans several domains of the specialty, including NMSC. In this paper, we present data from the pilot phase of the project, involving 7 units. Data collection took place as a snapshot audit in a 2-month discrete time period (from 13/09/2021 to 13/11/2021).

In total, we have recorded 540 NMSC cases. The majority were BCCs (372), with 168 being SCCs. About a 1/3 of the cases were diagnosed using dermoscopy, and around the same number of patients had biopsies before their treatment. We found that over a 1/3 of the included cases

had incomplete SCC excisions (when the tumours were looked under the microscope, they were found either at the cut margin or within less than 1mm of it). We have also noted that important clinical information was not recorded for SCCs (such as the T stage, which indicates the size of the cancer). The predetermined margin was also not available for over half of the cases.

The findings from this report will help the QOMS team to revise and improve the questionnaire. We will discuss with the British Association of OMFS, recommending support to clinicians for training in dermoscopy. We will evaluate the initial finding of the high incidence of incomplete excisions in a larger dataset that will include more units and of longer duration.

The overall aim of the QOMS initiative is to improve patients' outcomes and clinical care. This initial pilot phase provides reassurance that a continuous audit for all OMFS units can be achieved soon.

Background

Treatment of non-melanoma skin cancer (NMSC) represents a significant percentage of the workload in a typical UK OMFS unit. (8) Basal Cell Carcinoma (BCC) is the most common type, (9) followed by Squamous Cell Carcinoma (SCC), which, although less common, carries worse prognosis and can require more complex treatment. (1) NMSCs are usually the result of many years of sun exposure (ultra-violet) in fair-skinned individuals. Local services for NMSC can provide high quality management for most patients through a local skin MDT, and appropriate patients with more complex pathology can be supported by the Head and Neck multidisciplinary team and/or a tertiary specialist skin (Multidisciplinary Team) MDT. Due to the volume of patients, treating NMSC in a standardised fashion has significant health-economic implications and impacts on the local Trust's national cancer performance targets. Capturing outcome data for NMSC falls within the QOMS group of "high-volume surgical procedures with both high and low risk of complications". (10)

The two treatment options for NMSC that have shown safety and efficacy in multiple clinical trials are surgical resection and radiotherapy. Surgery is often the preferred option as it is generally simpler and more cost effective. When performed successfully, surgery can provide an excellent cosmetic result.

There are two types of surgery utilized for facial NMSC. The most commonly employed technique is surgical excision with a pre-determined margin. The second surgical option

is Moh's micrographic surgery, (9) but it is resource intensive. It is therefore reserved (in the NHS) for high-risk lesions, in high-risk areas (for example, recurrent basal cell carcinomas, or lesions located in the medial canthal region of the eyelids).

Squamous cell carcinomas can metastasize to the regional lymph nodes (a risk of around 20%) and tend to grow locally invading and destroying adjacent structures. The British Association of Dermatologists has published updated summary guidelines document for diagnosis and treatment of cutaneous SCCs. (1)

We applied a published pilot risk-adjustment model to the datasets of both SCC and BCC excisions. The models account for differences in the patient characteristics (age/gender) and tumour characteristics (core histopathological features). The risk adjustment models derive from an analysis of 3500 facial skin excisions undertaken recently in 3 NHS OMFS units. This paper represents the external validation of the BCC model and SCC model (11).

We present here the data captured around the treatment of NMSC. This represents the larger QOMS dataset to date and is a true reflection of current practice in the participating units. As the QOMS initiative is at its early stages, this report will become an extremely useful benchmark for when more UK OMFS units join the initiative and start contributing data.

Patients and Methods

Details about participating units and dates and specifics around data collection have been discussed in the organisational set-up section.

Desired QOMS outcomes for NMSC have been selected and agreed in several meetings amongst the QOMS core NMSC working representatives (P Kyzas and D Tighe) and following discussions with the BAOMS SSIG for skin cancer. The three main outcomes for this cohort are the rates of diagnostic biopsies, status of surgical resection margins and whether an unplanned re-operation occurred within 30 days of the index procedure.

We have also collected the following data for these patients:

1. Demographics
2. Site of surgery – using a standardised map of facial zones
3. Clinical pre-determined margin (in mm)
4. Type of repair following cancer ablation (primary closure, local flap, skin graft)

5. Preoperative clinical diagnosis
6. Method of diagnosis prior to definitive surgery (with emphasis as to whether dermoscopy and/or biopsy was carried out)
7. Final histological diagnosis and histology subtypes
8. TNM stage for SCC
9. Presence and details of high-risk features (both for SCC and BCC)

Results

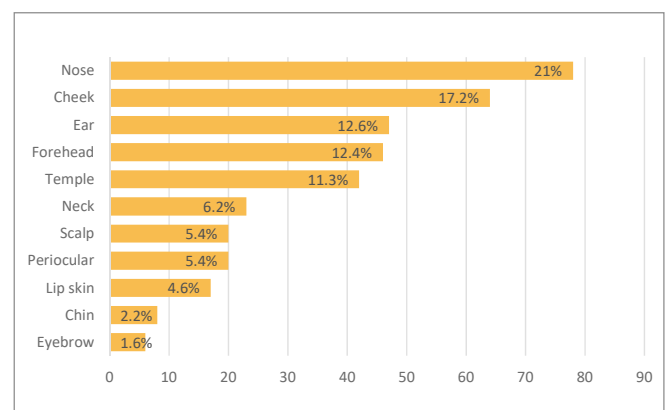
Seven OMFS units have provided data for a 2-month period, BAOMS-funded units provided data for the period between 13/09/2021 to 13/11/2021. As it is not uncommon for a patient to present with more than one NMSC (often multiple lesions are treated at the same sitting), data analysis was at lesion level rather than at patient level. This links with the desired outcomes described above. In total, we have recorded 540 NMSC cases. The majority were BCCs (372), with 168 being SCCs. We analysed the two tumour groups separately below.

Basal cell carcinomas

Most patients presenting with BCCs were elderly, with 68% of them being between 70-90 years old (223/372). Most patients were male (227/372, 61%). Lesions were mostly located on the nose (78, 21%), followed by the cheek facial unit (64, 17%). The ears, forehead and temple formed the remaining common location in the head and neck subsites (around 12% each) (*Figure 7.1*).

Figure 7.1

BCC location within subsites in the head and neck within the QOMS NMSC audit



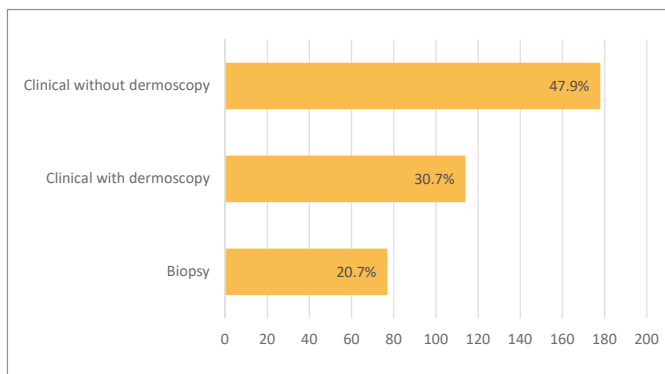
When available (N = 129, 34.7%), the most employed pre-determined margin of surgical excision was 4mm (91, 70.5%), followed by 3mm (25, 19.4%). The lack of documentation of a predetermined margin was the most frequent observation.

Primary closure was chosen as a type of repair in over half of the cases (55%), followed by local flap reconstruction (24%). A full thickness skin graft was selected in 9% of the cases.

In the diagnosis of lesion before treatment, clinicians have not used dermoscopy in most cases (48%) and have relied on their clinical impression. Dermoscopy was employed in 30% of the cases, whereas pre-operative

Figure 7.2

Pre-operative method of diagnosis for BCC



incisional biopsy was taken in 20% (Figure 7.2). Data was missing for 3 lesions.

Over 80% of the recorded BCCs were of the infiltrative histological subtype. A quarter of the lesions (96, 26%) were categorised as showing “high-risk” features, most of them (56%) due to the location of the lesion.

BCC Resection Margins

A small percentage (8%, 30 cases) had involved peripheral margins, and 8 cases (2%) had resection margins of <0.5mm. The total number of cases with <1mm peripheral margin histological clearance was 72 (21%). Similarly, a small percentage (10%, 34 cases) had involved deep margins, and 18 cases (5%) had a deep resection margin of <0.5mm. The total number of cases with <1mm deep margin histological clearance was 91 (26%). The number of cases in which both lateral and deep margins were involved was 26 (7%).

Reoperation. 5 cases had re-operation and 1 was within 30 days of the index surgery

Risk-adjustment

346/372 (93%) cases had complete data including margin status on which to model combined (peripheral & deep) margin status at the <0.5mm threshold. The risk-adjusted <0.5mm margin rate demonstrate marked differences to raw <0.5mm margin rates and this suggests substantial differences in the patient or tumour characteristics exist between units. (Table 7.1)

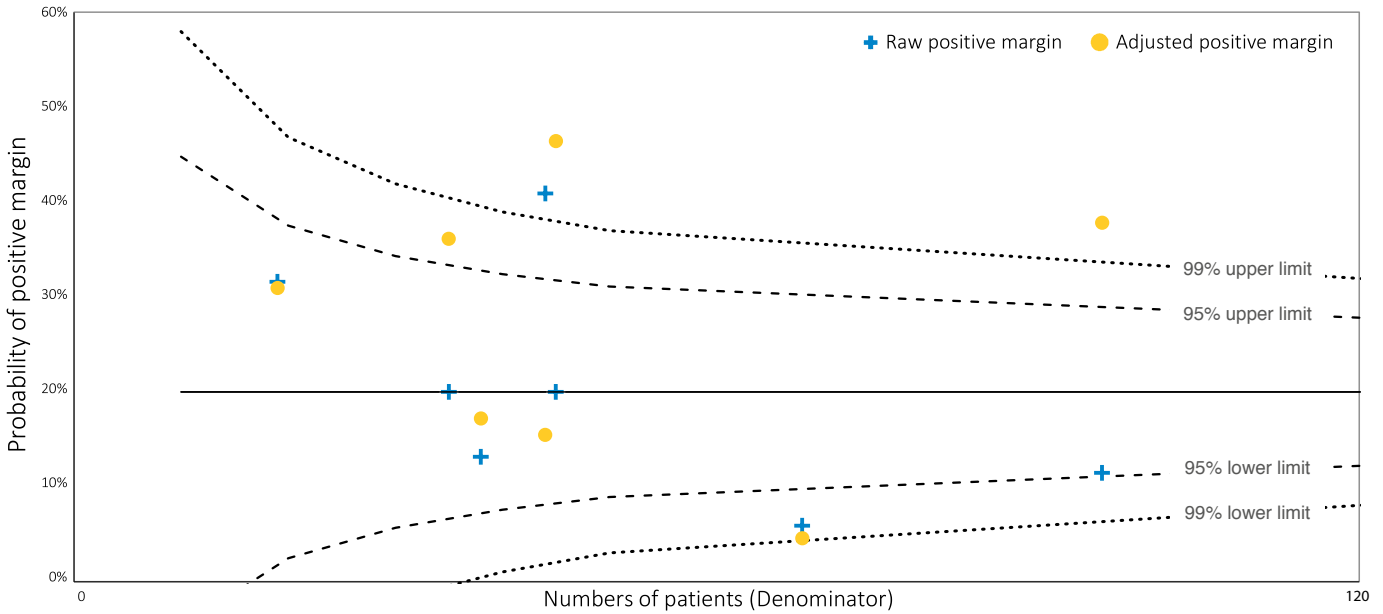
BCC risk adjusted margins (combined) at the 0.5mm threshold

Table 7.1

Organisation	Raw <0.5mm Margin	Numerator	Denominator	Predicted <0.5mm Margin	Risk Adjusted <0.5mm margin
OMFS-107	6%	4	68	13%	5%
OMFS-130	20%	7	35	6%	36%
OMFS-157	11%	11	96	3%	38%
OMFS-28	32%	6	19	11%	31%
OMFS-58	41%	18	44	27%	15%
OMFS-84	20%	9	45	4%	46%
OMFS-94	13%	5	38	8%	17%
Overall cohort	20%	29	147	10%	27%

Figure 7.3

Funnel plot showing BCC risk adjusted margins (combined) at the 0.5mm threshold



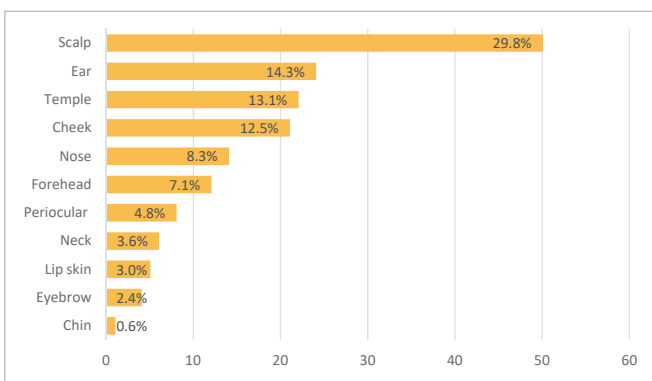
Squamous cell carcinoma

Patients presenting with SCC were generally the elderly, with 79% of them being between 70-90 years old (132/168). Most patients were male (134/168, 79%). Lesions were mostly located on the scalp (50, 30%), followed by the ear (24, 14%). The temple, and cheek formed the remaining most frequent locations (around 13% each) (Figure 7.4).

When reported (N = 60, 35.7%), the most employed pre-determined margin was 4mm (N = 45, 16%), followed

Figure 7.4

SCC location

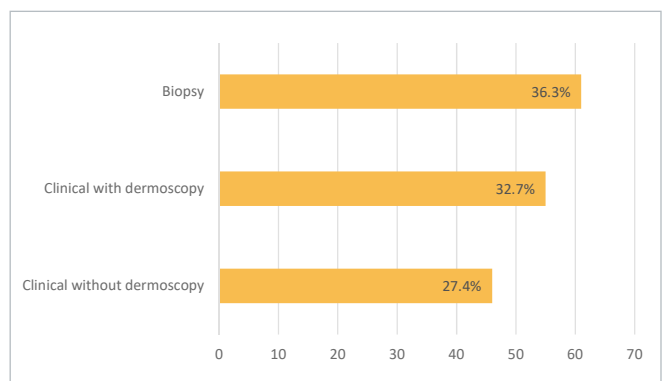


by 5mm (N = 15, 25%). The lack of documentation of a predetermined margin was the most frequent observation. Primary closure repair was possible in most of the cases (34%), followed by local flap reconstruction (28%). A full thickness skin graft was selected in 17% of the cases.

In the diagnosis of lesion before treatment, clinicians performed preoperative biopsies in the over a third of cases (36.3%) and have relied on their clinical impression in just over a quarter of cases (27.4%). Dermoscopy was employed in 32.7% of the cases (Figure 7.5).

Figure 7.5

Pre-operative method of diagnosis for SCC



The majority of SCC were moderately differentiated on histology (38%) and over 40% were T1 tumours. However, clinical staging was not recorded in over 20% of the cases. A high percentage of cases (64, 30%) were categorised as showing “high-risk” features, most of them due to depth of invasion (39, 43%) and T2 stage (21, 23%).

SCC Resection Margins

A small percentage (13%, 20 cases) had involved peripheral margins, and 5 cases (3%) had a resection margin of <1mm. The total number of cases with <1mm histological clearance was 25 (16%). A higher percentage (19%, 30 cases) had involved deep margins, and 11 cases (7%) had a deep resection margin of <0.5mm. The total number of cases with <1mm deep margin histological clearance was 59 (38%) (*Table 7.2*).

The number of cases in which both lateral and deep margins were involved was 8 (6%).

Re-operation

Four cases had re-operation and 1 was within 30 days of the index surgery.

Risk adjustment

135/168 (80.4%) cases had complete data on which to predict combined (peripheral and deep) margin status. The risk-adjusted margins demonstrate marked differences in raw <0.5mm margin rates, which are partially accounted for when the risk-adjustment process is applied – this suggests substantial differences in the patient or tumour characteristics exist between units. (*Table 7.3*)

Breakdown of SCC deep surgical margins

Table 7.2

Deep margin	N (%)
0 mm	30 (19.2%)
<0.5mm	11 (7.1%)
0.5-1mm	18 (11.5%)
1-5 mm	86 (55.1%)
>5mm	11 (7.1%)

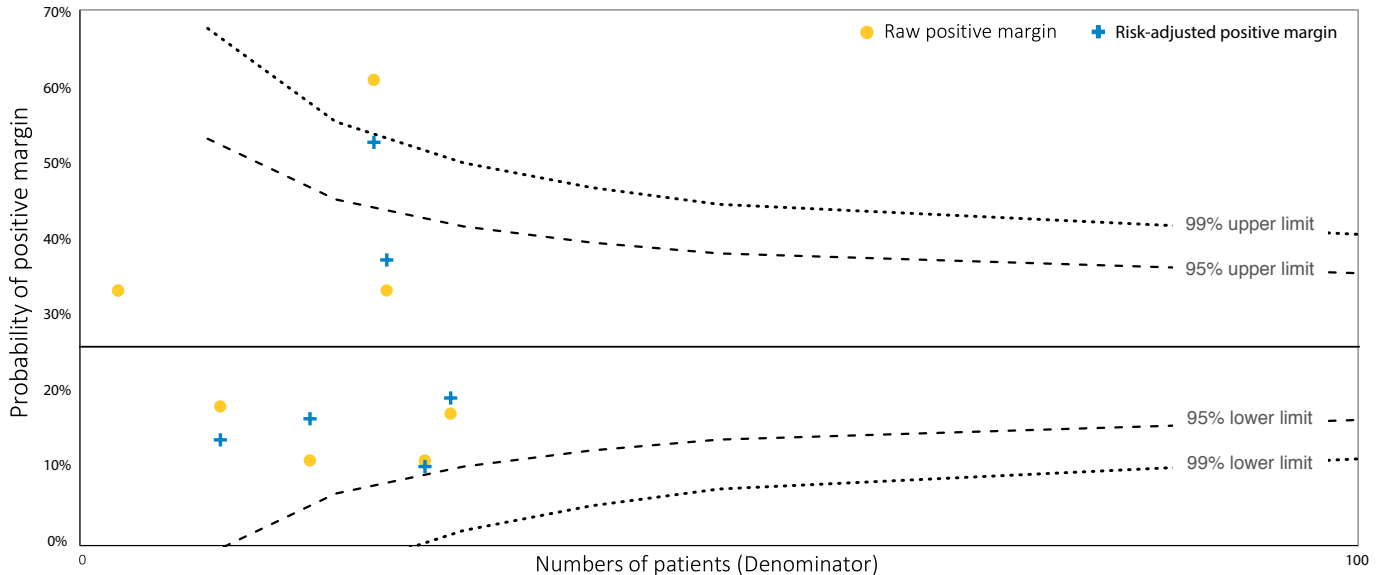
SCC risk adjusted margins (combined) at the 0.5mm threshold

Table 7.3

Organisation	Raw <0.5mm Margin	Numerator	Denominator	Predicted <0.5mm Margin	Risk Adjusted <0.5mm Margin
OMFS-107	11%	2	18	28%	17%
OMFS-130	18%	2	11	55%	14%
OMFS-58	61%	14	23	48%	53%
OMFS-84	33%	8	24	37%	37%
OMFS-157	11%	3	27	44%	10%
OMFS-94	17%	5	29	37%	19%
OMFS-28	33%	1	3	=0/3	
Overall cohort	26%	18	52	41%	25%

Figure 7.6

Funnel plot showing SCC risk adjusted margins (combined) at the 0.5mm threshold



Discussion

This inaugural report on the QOMS dataset for NMSC has revealed some key findings. These may have an element of selection bias, as only 7 out of the >100 UK OMFS units have participated in data collection; and these units share a common denominator when it comes to supporting the QOMS initiative and principles.

Our dataset included over 30% SCCs. This is higher than the prevalence of SCC in the overall NMSC population, where BCCs dominate with an incidence of over 80%. (8) The higher incidence of SCCs in the QOMS results is because data were collected in one 2-month snapshot period. Cutaneous SCCs have to be treated within 62-days of diagnosis, whereas BCCs are not subjected to such targets. It is therefore not surprising that SCCs are over-represented in short data-collection periods. This trend could reverse and normalise when data collection is continuous or if the snapshot audit periods are longer. One of the most interesting findings from the current data was the method of pre-treatment diagnosis for these lesions. Dermoscopy was used in 30% of the BCCs and 33% of the SCCs; however, a significant percentage of patients had pre-operative biopsies (36% for SCCs and 20% of BCCs). This approach adds significant cost and additional treatment delays, which are exacerbated by the volume of skin cancer patients. In an era where

cancer performance for many NHS Trusts depends on skin cancer treatment times these delays can be significant. Preoperative biopsies can be avoided in most cases, as the diagnostic accuracy of dermoscopy has been shown to be well over 90% (12) when performed by adequately experienced clinicians. There is a scope to promote dermoscopy training amongst OMFS skin cancer surgeons. There are several intensive customised; dermoscopy courses the BAOMS (via the skin SSIG) can guide clinicians towards them.

The location of the primary tumours was found to be in accordance with the literature, (1,9,10) with scalp and ear being the dominating areas for SCCs and nose-cheek being the most common locations for BCCs. The age of the included population was also in accordance with previous large case series.

Data capturing and recording on the selected predetermined clinical surgical margin was suboptimal. Data were available in less than half of the cases for both tumour groups. This information is crucial and links with the new BAD guidelines (1) in terms of treatment planning, especially for SCCs. One would expect this to be readily available from the operation notes. The QOMS project manager will liaise with the local data collectors and clinical teams to strengthen this crucial element of data capturing.

When it comes to the clinically meaningful outcomes, the most important finding was the high percentage of close or involved deep margins for SCCs. Involved deep margins were found in 19% of the cases, whereas in 38% of the tumours, the deep margin was <1mm. Incomplete excision of cutaneous SCCs has an increased risk of local recurrence, tumour progression, risk of metastasis and overall poor prognosis. (13) In case of incomplete excision, re-excision or adjuvant radiotherapy is recommended. In our dataset, the percentage of re-excision was very low with only one case performed within 30 days of the index procedure. It was possible that these patients were offered adjuvant radiotherapy (although this was not a data collection element on the current QOMS NMSC questionnaire), or that re-excision was delayed more than 30 days after the index procedure.

The issue of incomplete SCC excision identified here might be linked with two other findings from our dataset. Firstly, we have noted underreporting of the clinical T stage for SCCs. This has importance implications on surgical planning; the T stage is included in the updated BAD guidelines as a criterion for selecting the predetermined surgical margin. (1) We suspect that many of the missing values potentially refer to cT2 tumours as these are linked with a higher risk of incomplete excisions. (1) Secondly, we noted that primary closure was the most common way of reconstruction. Although subtle, this might indicate a more conservative excision approach, which can potentially be linked with involved margins and incomplete excision.

The inaugural QOMS NMSC report has several limitations. Firstly, as mentioned previously, there is a risk of selection bias due to the small number of the participating units. However, this is the pilot phase of the QOMS initiative, and we envisage that in the future, significantly more UK OMFS units will contribute data to the initiative. Secondly, the data capture period was short; this might have impacted on how representative the

sample population was. Ideally, data collection should be continuous, however there are implications of workload on data co-ordinators and the local clinicians. Thirdly, we have not collected information about adjuvant treatment (radiotherapy), but this will be added in the updated NMSC QOMS dataset. Finally, we have identified a higher than anticipated rate of incomplete SCC excisions; this needs to be verified in a future comprehensive data collection, as it has potential implications in patients' prognosis and health-economics.

In conclusion, we have presented here the first dataset from the QOMS NMSC national audit. This has revealed important practical findings, such as clinical staging and predetermined margin under-reporting, and crucial clinical outcomes such as a high incidence of incomplete SCC excisions and underutilisation of dermoscopy. These pilot data will reshape the future QOMS NMSC questionnaires, and we will feedback to our national association (BAOMS) with specific recommendations on how to improve clinical practice.

Next steps, future plans & initiatives

The QOMS NMSC questionnaire was very well received by participating units and data collection was encouraging. The QOMS NMSC core team will continue to collaborate with the BAOMS Skin SSIG to refine the questionnaires and produce the final version that reflects the evolving and maturing nature of this initiative. We anticipate that further training of the local data co-ordinators will be needed, with more support from the clinical team and this will form an integral part of the project development. Our long-term aspiration is to have representative data from all UK units that have a NMSC service. This, however, will depend on the availability funding for local data co-ordinators with good clinical support. Recommendation to BAOMS Skin SSIG to support the education and training of clinicians in dermoscopy.

Oncology and Reconstruction

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Part 1: QOMS Oncology & Reconstruction Registry

Authors: Tighe D, Kyzas P, McMahon J, Sassoon I, Puglia F and Ho M

Key points

- QOMS Oncology and Reconstruction registry can be judged a cautious success. This audit, at an early stage, is demonstrating characteristics of a specialty led robust, fair and sustainable system of quality governance (1160 entries reported)
- Data quality is acceptable (>95%) throughout most fields with some exceptions (incomplete data in method of flap monitoring (26%) and adjuvant treatment (40%))
- A complication rate of 40% is close to previously published benchmarking papers
- The positive margin rate was 14% with a predicted positive margin rate of 11% after risk adjustment
- Delay to adjuvant treatment was frequent, with only 12% making the 42-day target. The data analysed suggests that perhaps with the current working arrangements and resources available, the NHS is falling short of this standard/important cut-off timeline
- The average length of stay for patients who had head and neck reconstruction was 20 days and the predicted average length of stay after risk-adjustment was 10 days. The aggregate frequency of extended length of stay >50days was 2% in this phase of the national audit
- The overall flap success rate for the dataset was 96%
- 95% of patients were discharged back to their residence
- 7% of patients are recorded as deceased on 6-week follow-up

Lay summary

Complex treatment for head and neck (mostly mouth) cancer forms a significant component of the workload of major Oral and Maxillofacial Departments across the UK. This treatment often requires a complex skillset in removing cancerous growths in the mouth, face and jaws areas, and reconstruction with a varied approach to include microvascular surgery, dental implants and patient specific engineered implants when the facial

bones are involved. The overall success rate for cancer reconstruction in this period of our audit was 96%. Due to the complex and intricate nature of treatment, approximately 40% of patients unfortunately develop treatment related complications. Most patients stayed in hospital for 20 days after their operations and they were mostly discharged back home after this. A small group of patients were in hospital for more than 50 days (2%), after their operations, these were mainly due to complications which have developed during their care, highlighting the complicated nature of the treatment package required for their successful recovery. Seven percent of patients have been reported to have passed away at six weeks after their operation. The audit for the treatment of head and neck cancer by the Oral and Maxillofacial Surgery team can be judged as a cautious success, never before has such a large dataset of patient treatment outcome been collated across multiple centres in the UK, and as the dataset grows and matures, more meaningful and representative information will be produced to support the quality improvement process.

Introduction

In 2018 QOMS led a consultation, through the BAOMS forum, seeking views on desirable metrics to track quality of care in Oncology and Reconstruction. Leadership on what would represent 'a good metric' was provided by steering group at the time led by J McMahon and literature review. Proposed metrics were discussed between the Steering group, BAOMS Oncology and Reconstruction Subspecialty Interest Groups (SSIGs) in late 2018.

For metrics to be effective they must be measurable, reproducible, demonstrate variation between units, be amenable to change by service personnel, have baseline data available in the literature and must meaningfully impact patient outcomes. The Steering group also advocated for metrics which can be modelled to allow to account for variation in complexity of patient need care. The following quality-of-care indicators (three for each subspecialty) were chosen:

Oncology

- Complications within 30 days
- Lymph node harvest in a staging / therapeutic neck dissection
- Surgical Margin Status (positive margin <1mm).

Reconstruction

- Free flap outcomes (14)
- Length of Hospital Stay
- Time to radiotherapy

This chapter will have 2 parts:

- Part 1 presents aggregate raw outcome data from the 1st year of the audit and
- Part 2 presents unit level risk-adjusted outcome data for (all) Complications within 30 days, Surgical Margin Status (for HNSCC cohort), Length of Hospital Stay and Free flap complications (Complete failure only). The risk adjustment model development(s) are appended to the report.

Risk adjustment model development underlined the current variation in outcomes at different treatment centres. Complication rates varied in 6 UK OMFS units from 34-51%. (15) Length of hospital stay varied widely. (16) Surgical excision margin status varied 19-29%. (17) Flap failure rates also varied 2-8%. (18) We believe, within the limits of patient and tumour factors, these outcome metrics are amenable to improvement by the treating unit.

Data supporting the threshold of 18 nodes in a unilateral neck dissection lymph node count was derived from a systematic review published in 2019. (19) Time from surgery to radiotherapy of 6weeks (42 day) is a consensus target supported by a randomised control trial from Denmark. (20)

QOMS' key ambition is to capture and report unit level data. Clearly patient outcomes are not solely the determinant of an individual surgeon. Major cases are often undertaken by a pair of surgeons (perhaps of different disciplines working in the Head & Neck region) and many outcomes are significantly impacted by members of the anaesthetic, intensive care, medical and allied professional team.

At an early stage we understood that though the cohort receiving immediate free tissue transfer represent a 'high risk' group (for complications and positive margin status) the highest risk group are the patients receiving T3/T4 resections without immediate reconstruction; these patients are frequently deemed anaesthetically unfit for extended theatre times. In the same spirit, many "highest" risk free flap patients are not those also having a cancer excised; for example, those receiving surgery for osteoradionecrosis in heavily treated regions of the Head and Neck. Thus, there remains significant overlap in case-capture with majority of patients in the Oncology & Reconstruction registry having cancer ablation and immediate free tissue transfer; with an additional minority having just cancer ablation or free flap transfer to the head and neck region for different reasons. Complications within 30days could have been 'return

to theatre' but concern was expressed that this had the potential of missing some 'serious complications – Clavien-Dindo 3b' that were surgically managed in the maxillofacial clinic and/or ward setting.

Further, flap complications could have been 'Complete flap failure' which is usually due to microvascular anastomotic failure however, partial flap failure can be equally morbid to the patient and a flap outcome classification described in the literature could be validated within QOMS. (21)

Methods

Baseline data capturing the following features was filled prospectively

- Patient data: age, postcode, gender
- Lifestyle: alcohol and smoking
- Performance: WHO Zubrod status, and ACE-27 comorbidity score status
- Previous treatment history: Surgery or Radiotherapy to the ablation site
- Tumour factors: T classification (AJCC TNM v8), N classification (AJCC TNM v8), Depth of tumour
- Operation details: OPCSv4 surgical procedures including tracheostomy and free flap details.

At 6 weeks

- Length of Hospital Stay
- Margin Status (<1mm positive; 1-5mm close; >5mm clear)
- Time to radiotherapy in days (if indicated)

Results

At the time of writing, we have comprehensive reporting up to August 1st, 2022.

- Part 1 will focus on descriptive statistics including mention of missingness as a marker of 'completeness' of a care episode record, and indeed the rigour of the data collection process. All data will be presented as an aggregate.
- Part 2 will be addressed in a separate chapter and focus on brief presentation of data as either comparison of observations versus expected frequencies or risk-adjusted rates displayed as funnel plots for the key metrics for the participating units

Thirteen units had submitted data to the registry by August 1st, 2022. Contributions ranged from 10 (1%) to 242 (27%)

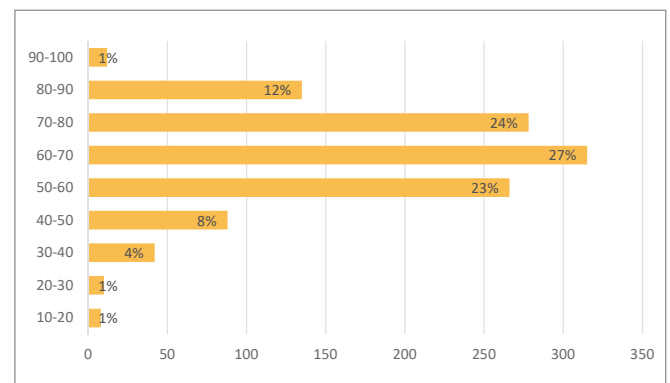
records (averaged: 68 records / unit, median: 44). Special mention is necessary about two units; OMFS-130 has appointed and paid for their own data co-ordinator and data collection has been prospective since August 2020; OMFS-161 requested QOMS to accept a 'bulk upload' of departmental audit data collected using their local database and includes a cohort prior to inception of QOMS. Transformation of a minority of the features was necessary to ensure compatibility of analysis with some loss of integrity of consistency of terms / sub terms in the process. 'Skin in the game' explains the observation that 2 of 3 of the next best contributing units are those of the BAOMS QOMS Clinical Lead and Deputy Lead, respectively. How this commitment to the project is transmitted across the entire group and beyond to new units in the future is a key concern of the Steering Committee.

A total of 1160 Oncology care episodes are present, of which 100% had some 6-week follow-up data completed. 99% of age and gender fields were completed. The age range was 10-95, mean 65 years (*Figure 8.1*) and the gender makeup was 55% male. Over 60% of patients

were current or ex-smokers and 11% were heavy drinkers (*Tables 8.1 and 8.2*).

Figure 8.1

Age deciles for Oncology and Reconstruction patients in this QOMS audit cycle



Smoking status for Oncology and Reconstruction patients in this QOMS audit cycle

Table 8.1

Smoking status	N (%)	Smoking status	N (%)
Current	303 (26.2%)	Never	417 (36.0%)
Ex-smoker	396 (34.2%)	Missing	42 (3.6%)

Weekly alcohol consumption for Oncology and Reconstruction patients in this QOMS audit cycle

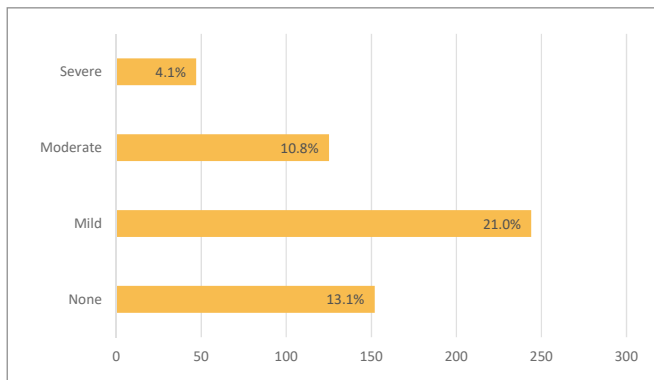
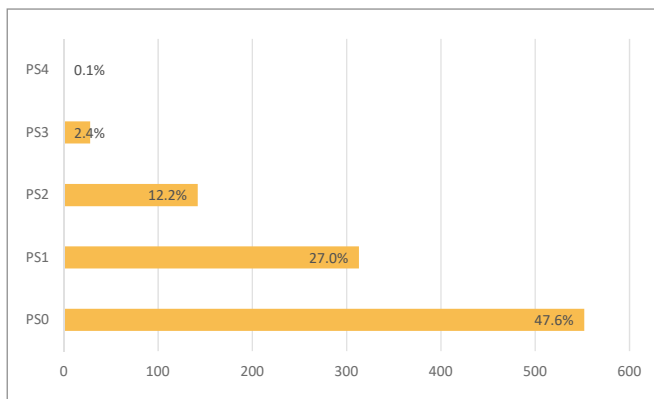
Table 8.2

Alcohol consumption	N (%)	Alcohol consumption	N (%)
None	341 (29.7%)	More than 40 units - Heavy	135 (11.7%)
Up to 14 units - Light	305 (26.5%)	Ex-heavy	30 (2.6%)
More than 14 units - Moderate	148 (12.9%)	Missing	191 (16.6%)

Patient performance and co-morbidity summaries were completed in 1036/1160 (90%). WHO status was present in all of this group and 568/1160 (49%) ACE-27 was completed. The majority of ACE-27 inputs were attributable to one unit (OMFS-161). Approaching 60% of patient care episodes were undertaken on WHO PS 0 or 1 status patients. (Figures 8.2 (a) – (b))

Figure 8.2

a) WHO Zubrod Performance Status (top) and b) ACE-27 (bottom) for Oncology and Reconstruction patients in this QOMS audit cycle

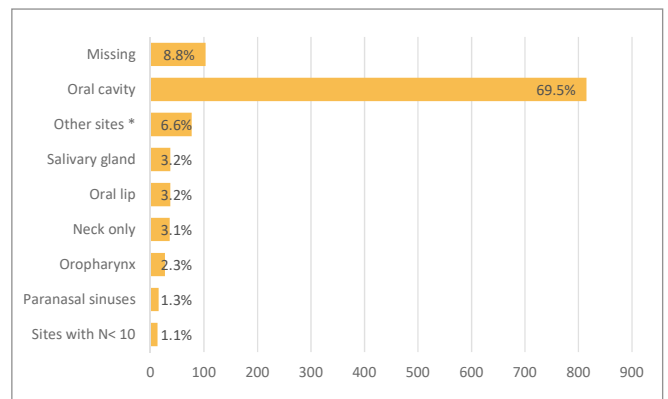


Anatomical subsite of surgery demonstrates, as expected that 70% of surgical episodes were to treat oral squamous cell carcinoma with a further 3% for mucosal lip primaries. (Figure 8.3)

The histology fields were completed in 98.8% of entries. The commonest histological diagnosis was SCC (Figure 8.4). When considering other types of cancers, the most common histology requiring Head and Neck surgery was melanoma (17.6%) then mucoepidermoid carcinoma (14.5%). (Figure 8.5)

Figure 8.3

Primary cancer site location for Oncology and Reconstruction patients in this QOMS audit cycle



(Other sites include orbit, skullbase and temporal bones... sites with n <10: supraglottis, nasopharynx, hypopharynx, and Larynx)

Figure 8.4

Diagnosis groups for Oncology and Reconstruction patients in this QOMS audit cycle

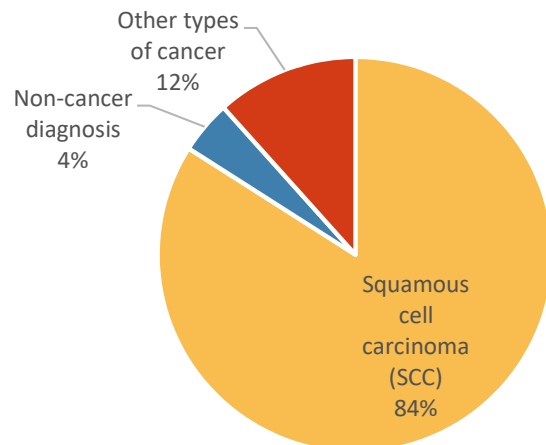
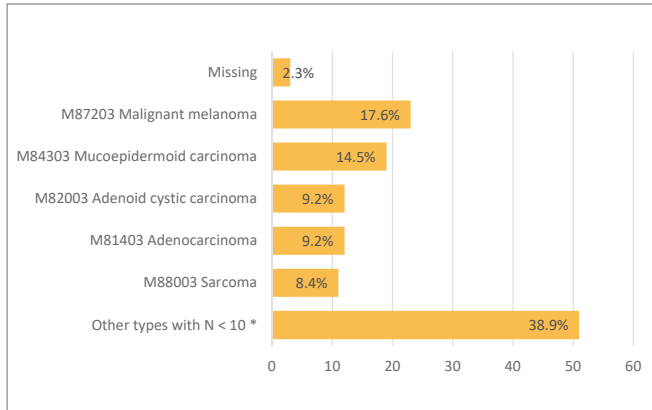


Figure 8.5

Other types of cancers (non-SCC) for Oncology and Reconstruction patients in this QOMS audit cycle

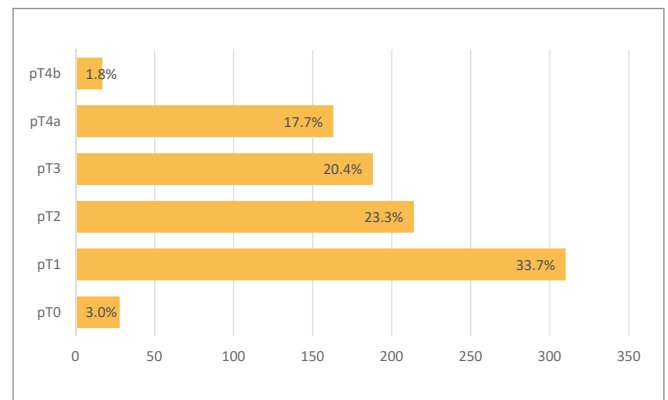


(* M80003 Neoplasm – malignant, M80050 Clear cell tumour – NOS, M80413 Small cell carcinoma, M81406 Adenocarcinoma – metastatic, M81473 Basal cell adenocarcinoma, M84013 Apocrine adenocarcinoma, M85603 Adenosquamous carcinoma, M88903 Leiomyosarcoma, M89400 Pleomorphic adenoma, M09503 No microscopic confirmation - clinically malignant tumour (cancer), M81233 Basaloid carcinoma, M89003 Rhabdomyosarcoma, M92203 Chondrosarcoma, M80106 Carcinoma – metastatic, M85623 Epithelial-myoeipithelial carcinoma, M82473 Merkel cell carcinoma, M80903 Basal cell carcinoma, M85503 Acinar cell carcinoma, M89413 Carcinoma in pleomorphic adenoma, M85253 Polymorphous low grade adenocarcinoma)

Classification (AJCC v8 TNM) was present in 90% of records, and over 57% of cases were T1 or T2 with 180/1160 (19.5%) being T4a or T4b. (Figure 8.6)

Figure 8.6

Pathological tumour staging



734/1160 (63%) of patients had a neck dissection recorded of which 677 (58%) were elective and 51 (5%) was undertaken as a secondary procedure. (Table 8.3)

Neck dissection

Table 8.3

	N (%)
An elective neck dissection carried out at the same sitting as the resection (+/- reconstruction) of the primary tumour	677 (58.4%)
An elective neck dissection carried out after resection of the primary tumour as a secondary procedure	48 (4.1%)
A sentinel-node-biopsy-assisted neck dissection	6 (0.6%)
A completion neck dissection after a positive sentinel lymph node biopsy	3 (0.3%)
Not applicable	424 (36.7%)

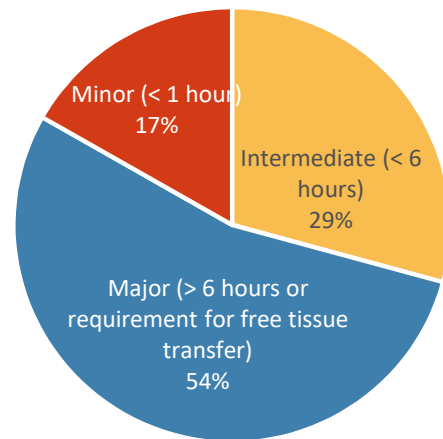
Scale of surgery field was missing in 14/1160 (1%). Just over half of patients (53%) received immediate free tissue transfer or had surgery lasting >6hours (Figure 8.7). 30% of patients had an elective tracheostomy. 54% of patients had surgery that involved the surgical risk of a mucosal incision/ flap inset coincident with a neck dissection, suggesting an increased (“high”) risk of salivary leak.

Complication outcomes

Complications were recorded comprehensively with minimal missingness (1/1160, <0.1%). Complications were frequent 460/1160 (40%). Surgical complications accounted for over half of complications. Wound dehiscence, haemorrhage (or haematoma) and flap problems totalled 243/460 complications. Pneumonia and delirium accounted for the commonest systemic complications. (Table 8.4) Further clarity needs to be sought about complications not otherwise specified or “other” 130/1160.

Figure 8.7

Scale of surgery for Oncology and Reconstruction patients in this QOMS audit cycle



Complications within 30 days after surgery for Oncology and Reconstruction patients in this QOMS audit cycle

Table 8.4

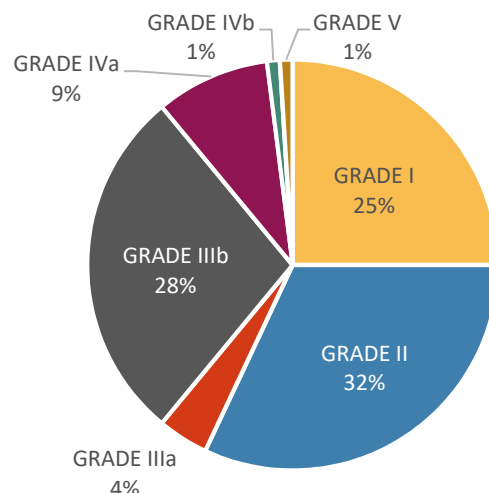
Early complications	N (%)	Early complications	N (%)
No complication	595	Haematoma	24 (5.6%)
“Other”	130 (30.1%)	Delirium	19 (4.4%)
Wound dehiscence	53 (12.3%)	Wound infection - donor site	16 (3.7%)
Problem with flap	46 (10.6%)	Wound infection - recipient site	13 (3.0%)
Pneumonia	38 (8.8%)	Orocutaneous fistula	13 (3.0%)
Haemorrhage	36 (8.3%)	Other complications*	44 (10.2%)

(* Atrial fibrillation, Cardiac arrest, Unspecified respiratory failure, Chyle leak, Neck abscess, Myocardial infarction, Congestive cardiac failure, Pharyngocutaneous fistula, Carotid blowout, Deep vein thrombosis, Pulmonary embolism, Gastrostomy complications, Urinary retention, Alcohol withdrawal – DTs, Septicaemia, Pneumothorax, Upper gastrointestinal bleed, Pancreatitis, C. Difficile-related complication)

The Clavien-Dindo Classification was used to grade severity of complications and was completed in 345 / 460 (75%) entries. (22) Clavien-Dindo grade IIIb represents return to theatre and occurred in 95/345 (27.5%) of documented complications or in 95/1160 (8.1%) of care episodes. Grade V represents in-hospital death and occurred in 2/1160 (0.2%) which needs reconciling with the discharge data presented opposite (Figure 7.8).

Figure 8.8

Clavien-Dindo grade of the most severe complications for Oncology and Reconstruction patients in this QOMS audit cycle



Lymph node yield

Of 1160 records, 728 records were recorded as either having a completion neck dissection or an elective neck dissection, of which 163 (22%) were missing nodal counts. The nodal counts differed if the neck dissection was carried

out at the time of tumour resection or delayed (mean 27.5 or 27.25, median 27 and 20 respectively) of which, in those with positivity, a mean of 2 nodes were positive. Node count was less than the minimum target of 18 nodes in 97/523 (18%) of immediate neck dissections and 9/31 (30%) of completion neck dissections (*Table 8.5*).

Neck dissection nodal count: primary neck dissection vs. staged/delayed neck dissection

Table 8.5

	N	Min	Max	Mean	Median	95% CI	SD	Node count ≤18	%
An elective neck dissection at time of resection (+/- reconstruction) of the primary tumour									
No. of nodes (Left)	276	0	76	28	27	25.0 to 29.0	14	67	24%
No. of nodes (Right)	247	0	76	28	27	25.0 to 29.0	14	26	11%
No. of positive nodes (Left)	154	0	28	2	1	1.0 to 2.0	3		
No. of positive nodes (Right)	113	0	15	2	2	1.0 to 2.0	2		
An elective neck dissection as a secondary procedure									
No. of nodes (Left)	16	0	62	27	21	16.0 to 33.0	18	7	44%
No. of nodes (Right)	15	6	42	22	22	13.7 to 29.4	11	2	13%
No. of positive nodes (Left)	9	0	8	2	2	1.0 to 3.0	2		
No. of positive nodes (Right)	11	1	5	2	1	1.0 to 2.1	1		

Margin data

Of 920/1160 with a T classification recorded, 220 (22%) had missing margin data. The overall (either mucosal or deep) <1mm rate was 15%. The mucosal margin <1mm rate was 66/700 = (9%). The deep <1mm rate was 109/700 (16%). (*Table 8.6*)

Free flap outcomes

Free flap outcomes were completed in 557/581 (96%) cases recorded as immediate flap reconstruction cases. QOMS aspires to 100% data completion on this key metric.

Reassuringly for integrity of the process, 27/581 (4.6%) of free flaps failed completely which is almost exactly the frequency of the related publication on which our risk-adjusted Cumulative Sum Chart methods is based (4.7%) (*Table 8.7*). Although data completeness was poor (54% completed), clinical and non-invasive monitoring of free flaps were apparently the commonest strategy (38%) to monitor flaps.

Postoperative length of hospital stay and discharge

Length of hospital was reported in 95% of records (mean 11.2 days, median 8 days, and range 2-346 days) and of these 18/1024 (2%) patients were recorded to stay of 50 days which is well within the 5% expected rate. 96% of patients went home on discharge. (*Table 8.8*)

7% of patients are recorded as deceased on 6-week follow-up which is high and does not correlate well with the 2/1160 patients entered as having a Clavien-Dindo Grade 5 complication (mortality) at 30 days. The literature suggests 0.5-2% 30-day mortality for major head and neck surgery. It would therefore be important for data collected within QOMS to be used in conjunction with the National Consultant Information Programme (NCIP) portal data which has the advantage of input from the Office of National Statistics for community/out of hospital mortality.

Pathological T stage and their correlation with resection margin clearance

Table 8.6

Pathologic T stage	Closest deep margin (mm)			Closest mucosal margin (mm)		
	<1mm	1-5mm	>5mm	<1mm	1-5mm	>5mm
Missing	3	0	2	2	1	3
Not applicable/ Not available	1	0	1	1	1	0
pT0	3	2	5	2	3	5
pT1	8	80	147	7	113	119
pT2	15	63	105	12	75	97
pT3	18	59	66	7	51	86
pT4a	24	36	59	13	51	57
pT4b	5	2	3	2	5	3
Total	76 (6.6%)	242 (20.9%)	387 (33.4%)	45 (3.9%)	300 (25.9%)	370 (31.9%)

Flap outcome at discharge for Oncology and Reconstruction patients in this QOMS audit cycle* (14)

Table 8.7

Outcome category	Outcome	N (%)
1a	Complete success	511 (91.7%)
1b	Partial success with loss of some components of the flap, but no secondary reconstruction or prosthesis not required	15 (2.7%)
2a	Partial failure requiring a second flap (free or pedicled) to rehabilitate defect	4 (0.7%)
3a	Complete flap failure requiring a second flap (free or pedicled) to rehabilitate defect	19 (3.4%)
3b	Complete flap failure requiring no further reconstructive or prosthetic rehabilitation	7 (1.3%)
4	Failure to establish reconstruction	1 (0.2%)

*Data presented represents completed records. Flap outcome data was not applicable/available for n = 505 patients.

Discharge destination of patients following reconstructive/major head and neck surgery

Table 8.8

Discharge Destination	N (%)
Usual place of residence	1,019 (96.0%)
Other discharge destination *	15 (1.4%)
Missing	28 (2.6%)

(* Local area residential accommodation i.e., where care is provided, NHS - ward for general patient or the younger physically disabled, Temporary place of residence, NHS - care home, not applicable, non-NHS run care home, Repatriation from high security psychiatric accommodation in an NHS Hospital Provider)

Adjuvant radiotherapy

Radiotherapy and/or chemo-radiotherapy were indicated after surgery in 51% of patients. 430/1160 (37%) of patient cases did not report data in relation to adjuvant therapy (Table 8.9). There were large variations between participating hospitals, in both number of cases and in the starting time of adjuvant treatment after surgery. (Figure 9.9) 39/322 (12%) of those for whom data was available started adjuvant treatment within 42 days, and 139/322 (43%) started adjuvant treatment within 56 days. The mean time taken to start adjuvant treatment was 52days (range 18-188 days).

Table 8.9

Adjuvant therapy for patients who had undergone major head and neck surgery**

Adjuvant therapy	N (%)
Radiotherapy (RT) only	251 (39.7%)
Chemo-radiotherapy (CRT)	71 (11.2%)
No	310 (49.1%)

**Data presented in Table 7.11 represents only completed records. The information was "not applicable" or available for n=430 patients.

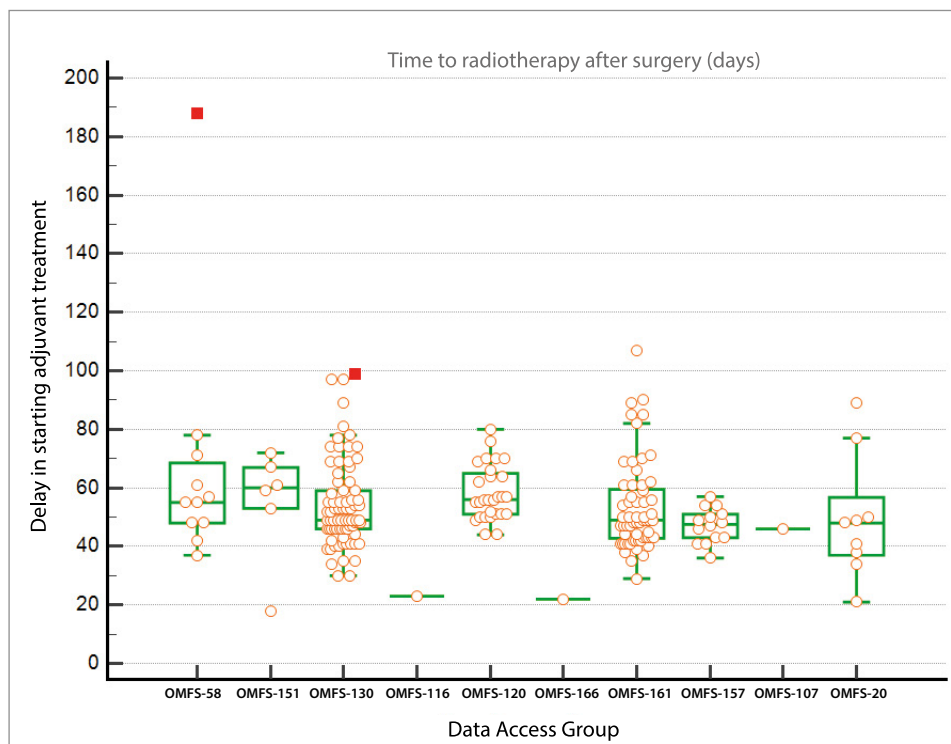


Figure 8.9

Time between surgery and the start of adjuvant therapy by contributing hospitals

Discussion

QOMS Oncology and Reconstruction Registry is an ambitious component of the QOMS project. It contains over 359 fields, embedded risk calculators for 4 of 6 key outcome metrics, and over 1000 care episodes in the 1st year of engagement. Appointment of data co-ordinators for 3 years suggests there is medium term resilience in this effort.

Data quality is acceptable (>95%) throughout most fields with some exceptions (missingness in flap monitoring (26%) and adjuvant treatment (40%)). Especially for key metrics QOMS steering group underscores the need for 100% case ascertainment, for example the free-tissue transfer outcomes were recorded in 96% at the time of writing which is suboptimal. In the 2nd year of the programme a stronger link between the steering group,

data co-ordinators and QOMS Local Leads will facilitate improvement in case ascertainment.

Further refinement of the list of complications is a required to aid analysis, though it is encouraging that the burden of collecting 'all complications' is being borne by data co-ordinators. A complication rate of 40% is close to previously published benchmarking papers. (15) Discrepancy between Clavien-Dindo Grade 5 (mortality) and the alive/dead 6-week follow-up status is critical to reconcile and will be a future priority handed to the local clinical and data co-ordinator teams, however with wider roll-out of the NCIP portal in England, this will hopefully improve over the coming years.

Delay to adjuvant treatment was frequent, with only 12s% making the 42-day target, though data completeness for this metric was poor (73%). We propose the addition of a further target, 56 days which may be more suitable for the cases delayed by the need to de-calcify bone resections. 43% of patients met the 56-day treatment target. The impact of delay to the start of adjuvant radiotherapy beyond 42 days has clear implications on disease control and survival. (23) The data presented suggests that with the current working arrangements and resources available, the NHS perhaps is falling short of this standard/important cut-off timeline. Feedback to

the multidisciplinary teams and colleagues nationally through BAHNO may be a meaningful first step in working to improve this. The concept of treatment package time perhaps should be considered as a further metric associated with the time from surgery to commencement of adjuvant treatment. (24)

95% of patients were discharged back to their residence. A crude threshold of 5% may serve as an alarm limit if this were to be adopted as a further metric for inclusion in QOMS Oncology and Reconstruction audit. An alternative metric for consideration could be, again at the 5% threshold, extended length of hospital stay of >50days. The aggregate frequency of extended length of stay >50days was 2% in this phase of the national audit.

Conclusion

QOMS Oncology and Reconstruction registry can be judged a cautious success. Despite the 1160 entries reported, it must be recalled that majority of these cases came from 5 units, 3 of whom receive financial support to fund QOMS data co-ordinators. We hope steady contributions from the remaining units over the next 2 years will increase the dataset further, provide more mature and in-depth analysis. We turn attention to risk adjustment of 4 of 6 chosen metrics.

Part 2: Oncology and Reconstruction - Risk adjustment

Introduction

Risk-adjustment models can be used to track quality of care in time referencing current activity to a target or benchmark. The benchmark is, in effect, derived from the dataset used to develop the model. The datasets in question are multicentre prospective clinician entered audits done in UK OMFS / ENT units. (15–18)

No model can be perfect, indeed ‘excellent models’ can usually be ascribed to easily identified factors that could act as surrogates for the outcome of interest. For imperfect models, some of the variation in outcome will be seen to be due to unmeasured or unmeasurable factors. Data collection of agreed factors can differ because of how staff use (complicated) data entry platforms, and this may affect data quality. Different characteristics in regional or hospital specific healthcare delivery may not be part of model build and understanding this may necessitate multi-level or hierarchical modelling. Completely random influences will present over time. Statistical approaches may be employed to quantify and/or adjust for random and non-random variations and known model biases during the risk-adjustment process.

There are two important aspects of model performance: calibration and discrimination. Calibration is the accuracy of a model in estimating an outcome of interest. Inaccurate calibration introduces a bias. The extent of bias depends on the calibration of the model, and this may need to be checked by hospital and/or diagnostic (sub) groups, to confirm model fitting. Discrimination is the probability that a model applied to a pair of individuals with and without an adverse outcome, gives a higher probability (above a cut-off) to the individual with the outcome, and a lower probability (below a cut-off) for other without the outcome. A model no better than random choice will have a 0.5 probability of correctly assigning probability above / below a cut-off correctly, irrespective of its calibration.

Common statistical tests employed for measuring calibration of a classifier model include the ‘goodness of fit’ test, such as advocated by Hosmer & Lemeshow, in which calibration is checked at each decile of risk, as determined by the model. The Briers (or scaled Brier’s) test is another alternative ([see Appendix](#)). A classifier models’ ability to discriminate is usually tested using the Receiver Operator Curve and C-Statistic (or Area under the Curve Statistic). A model with good discrimination will have a value >0.8, fair >0.7 and weak >0.6. Precision is

the probability of a positive prediction being an observed instance and Recall (or sensitivity) is the probability of an observed instance being assigned a positive prediction. The F1 score represents a discrimination measure that combines precision and recall ([see Appendix](#)).

Applying risk adjustment methods to outcome data can be done in cross-sectional or longitudinal methods. Cross-sectional approaches include the funnel plot and less desirably, league tables. Longitudinal methods follow activity in time and have the virtue of potentially identifying (almost) contemporaneous changes in performance (relative to the benchmark). Cumulative Sum charts (CuSUM) charts, which are a form of process-control statistics, are increasingly employed as a longitudinal method in the clinical quality assurance in setting.

Cross-sectional and longitudinal displays of risk-adjusted patient outcomes enable unit performance comparison with a benchmark, provided by the risk-adjustment model estimates, and usually also present control limits often of 2 and 3 standard deviations from the benchmark. An observation of an event frequency within control limits is described as an “inlier”, where the difference between the observation and the prediction is within the realm of a reasonable chance occurrence. In contrast, a frequency placed outside these control limits is described as an “outlier”, as the observation is likely not due to a chance occurrence. The statistical “outlier” may or may not be a clinical “outlier” in terms of clinical practice.

When outcome monitoring is undertaken, there is a responsibility to act in a considered, timely and appropriate manner to address whether there is a data and model related anomaly, or a clinical issue. QOMS will develop a strategy to affect this in Year 2. Further, in Year 2 we will develop a plan to ‘refresh’ the models based on newly acquired data because this ‘screening process’ is only as good as data quality and completeness, both of the model build stage, and prospective quality assurance process. Alerts of performance are often a result of shortcomings of this process, which need thorough scrutiny before judging true improvement or deterioration of a risk-adjusted clinical outcome.

We are in the 1st iteration of the QOMS report, and we aim to present high-quality outcome data that follows peer-reviewed exemplar processes of quality control in surgical performance. We follow a processes outlined in the literature (25) to judge thresholds at which unit level data and risk adjustment processes can be deemed sufficiently robust to proceed to presentation of comparative data.

There are currently aspects of this project that are attempting new methods or new applications of currently deployed methods of measuring quality of care. We follow guidance for validating models and constructing funnel plots for binary outcomes, but we are not aware, at the time of writing, of similar processes to follow for continuous outcomes (such as length of hospital stay) which will be outlined ([see online technical appendices](#)). We have adapted the CuSUM methodology (26) for tracking hospital mortality, substituting free-flap failure as the outcome variable.

In relation to binary outcomes Verberg (25) proposes the following 6 steps be followed in compiling graphics (such as funnel plots) when presenting comparative data on unit performance:

- (1) defining policy level input
- (2) checking the quality of models used for case-mix correction
- (3) examining whether the number of observations per hospital is sufficient
- (4) testing for overdispersion of the values of the quality indicator
- (5) testing whether the values of quality indicators are associated with institutional characteristics
- (6) specifying how the funnel plot should be constructed.

Step 1 addresses the considered choice of metrics outlined in the foreword and report introduction, in addition to the

chapter introduction. Step 2 is contained in the scientific papers describing the validation processes of the risk-adjustment models. We are in the process of further validating these models on the QOMS dataset, in effect external validation, the reports of which will be appended to this report. We will set the minimum threshold of data contribution necessary before presenting outcome data, because too few cases invites randomness to a degree that could misrepresent true performance reporting. Statistical processes to identify gross variation in outcomes, despite risk adjustment processes applied, might lead to resetting of the 95% and 99% confidence intervals and where this is done it will be openly acknowledged. Of interest to the steering group, the readership and perhaps commissioners, is the association of risk-adjusted outcomes to institutional characteristics such as case-volume, numbers of surgeons and case-mix aspects of the patient population. Our organisational questionnaire, submitted early in the 1st year of data collection, should provide the necessary data to complete this phase of the quality assurance in the near future. Finally, the funnel plot construction including choice of benchmark, control limits (and their shape) and presentation of non-included data will be applied.

Complications

All complications are risk adjusted using 4 methods outlined in REDCap and past publications. (15–18,24) The summary statistics for the risk-adjustment models employed are presented (*Table 8.10*).

Summary of the models' performance for Oncology and Reconstruction patients in this QOMS audit cycle

Table 8.10

Metric	Classifier	Sensitivity	Specificity	Accuracy	C Statistic	Confusion matrix		
						Observed 0	Observed 1	
Complication with 30 days	Neural Network	0.82	0.75	0.78	0.85	Observed 0	105	39
						Observed 1	23	118
LoS <15days	Decision Tree	0.8	0.78	0.8	0.77	Observed 0	484	33
						Observed 1	104	90
Positivity of Surgical Margins	Bayes Classifier	0.58	0.77	0.75	0.7	Observed 0	66	230
						Observed 1	50	768
Free flap failure	Deep Forest	0.96	0.058	0.54	0.66	Observed 0	860	658
						Observed 1	34	41

The risk adjusted 30-day complication rate for each unit is demonstrated below (Table 8.11) and funnel plot

to compare risk adjusted and raw complication rates between units has been presented in Figure 8.10.

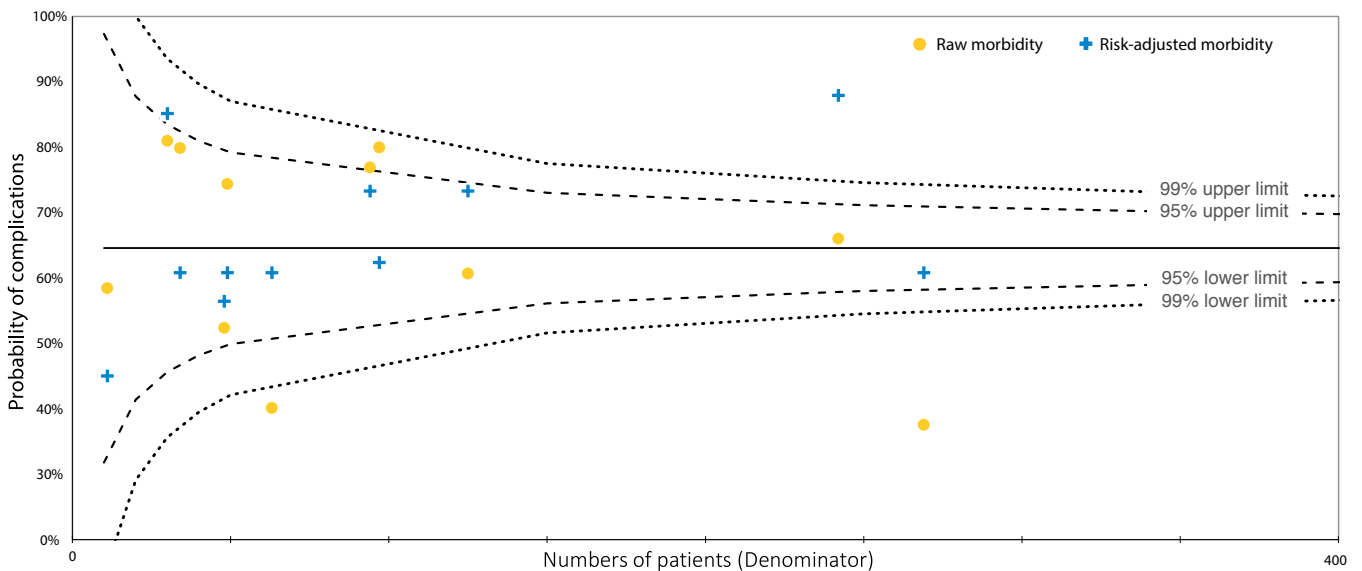
Unit-level rate of complication 30 days after surgery performance for Oncology and Reconstruction patients in this QOMS audit cycle

Table 8.11

Organisation	Raw 30d Complication Rate	Numerator	Denominator	Predicted 30d complication	Adjusted 30d Complication
OMFS-107	83%	25	30	37%	105%
OMFS-116	64%	7	11	62%	48%
OMFS-120	66%	82	125	42%	73%
OMFS-130	45%	122	269	49%	43%
OMFS-151	78%	38	49	49%	74%
OMFS-157	58%	28	48	52%	53%
OMFS-161	70%	170	242	36%	91%
OMFS-166	82%	80	97	48%	80%
OMFS-20	48%	30	63	49%	45%
OMFS-58	80%	75	94	42%	89%
OMFS-84	82%	28	34	49%	79%
Overall cohort	69%	137	218	47%	70%

Figure 8.10

Funnel plot to compare risk adjusted and raw complication rates between units between 95% alert and 99% alarm limits



Length of stay

Length of hospital stay data is risk adjusted after excluding those cases that stayed >50 days. To the remaining cases a decision tree is applied to identify which patients are

expected to stay up to 15 days postoperatively in hospital, and which are expected to stay beyond 15 days. (16)

The decision tree relies upon (in order of importance) tracheostomy, WHO status of patient, age (62yr cut-off), T

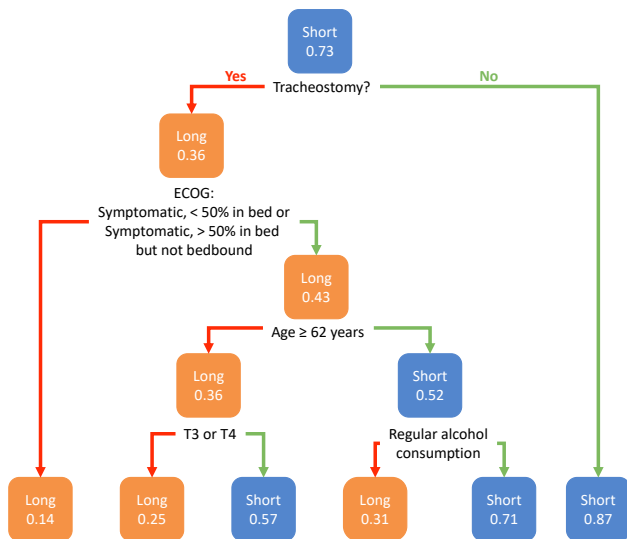
Classification of tumour and alcohol intake.

Thereafter, in the cohort expect to stay ≤ 15 days data is further analysed using a linear regression algorithm which relies upon alcohol status, age, tracheostomy status, T classification of tumour, “high risk status” and scale of surgery.

Figure 8.11 demonstrates each unit’s ‘as expected’ cohort when either the decision tree selects < 15 days and this is observed or selects > 15 days and this is also observed.

Figure 8.11

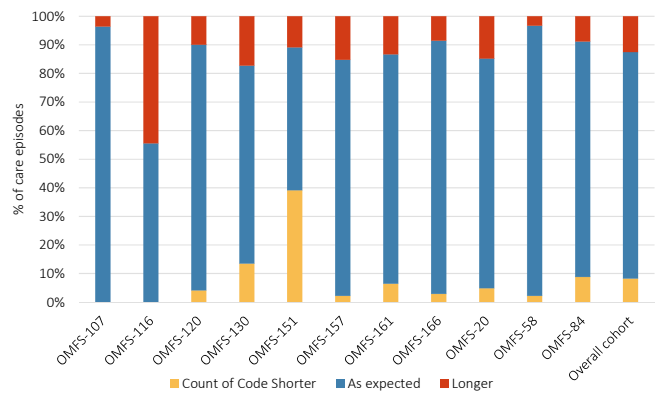
Decision tree for length of stay



Reproduced from: Tighe et al. (2019) Br J Oral Maxillofac Surg. 57(9):866-872. doi: 10.1016/j.bjoms.2019.07.007

Figure 8.12

Length of stay in each OMFS unit compared to the predicted model performance



Further breakdown of length of stay data by unit (Extended LoS (>50 days) = 0)

Table 8.12

Organisation	Observed LoS (Mean (SD))	Predicted LoS (Mean (SD))	Average of Extended LoS (>50 days)
OMFS-58	6.80 (9.10)	5.29 (2.90)	3.2%
OMFS-151	16.22 (11.20)	8.17 (4.08)	1.8%
OMFS-130	13.79 (9.96)	7.66 (3.03)	2.6%
OMFS-166	18.90 (14.14)	7.20 (2.49)	0.0%
OMFS-120	7.74 (7.57)	5.35 (2.75)	0.8%
OMFS-166	9.99 (8.84)	7.60 (3.67)	1.1%
OMFS-161	7.79 (9.80)	5.60 (3.46)	1.7%
OMFS-84	8.03 (8.34)	6.10 (3.51)	0.0%
OMFS-157	11.24 (10.45)	6.62 (3.16)	2.0%
OMFS-107	3.43 (4.30)	3.93 (1.68)	0.0%
OMFS-20	9.08 (7.61)	5.90 (3.03)	1.3%
Overall cohort	10.07 (9.82)	6.30 (3.34)	1.8%

Resection margin data for head and neck / oral cancer resection

The cut-off for a positive margin (either mucosal OR deep) was 1mm.

A Bayes Classifier is used to generate probabilities of a positive margin (either mucosal and/or deep) based on

T classification, presence of extra-capsular spread and anatomical sub-site of surgery (Table 8.13) and a funnel plot to compare risk adjusted and raw <1mm excision margin status after excision of HNSCC by treating units is presented in Figure 8.13.

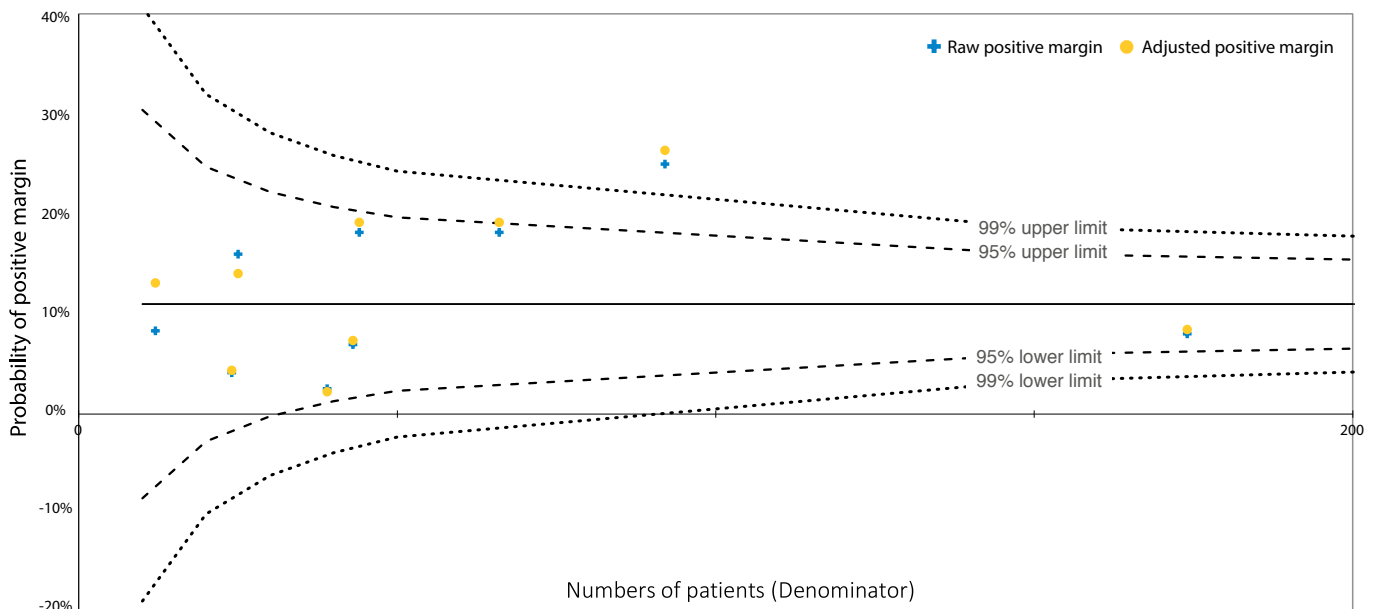
Probabilities of a positive margin (either mucosal and/or deep) based on T classification, presence of 2194 extra-capsular spread and anatomical sub-site of surgery

Table 8.13

Organisation	Raw Positive margin	Numerator	Denominator	Predicted positive margin	Adjusted positive margin
OMFS-107	8%	1	12	9%	10%
OMFS-120	25%	23	92	10%	26%
OMFS-20	7%	3	43	10%	7%
OMFS-84	16%	4	25	12%	14%
OMFS-58	18%	8	44	10%	19%
OMFS-157	3%	1	39	12%	2%
OMFS-130	8%	14	174	10%	8%
OMFS-151	4%	1	24	10%	4%
OMFS-166	18%	12	66	10%	19%
OMFS-116	33%	3	9	12%	29%
OMFS-161	15%	29	192	11%	14%
Overall cohort	14%	27	147	11%	

Figure 8.13

Funnel plot to compare risk adjusted and raw <1mm excision margin status after excision of HNSCC by treating units (between 95% alert and 99% alarm limits)



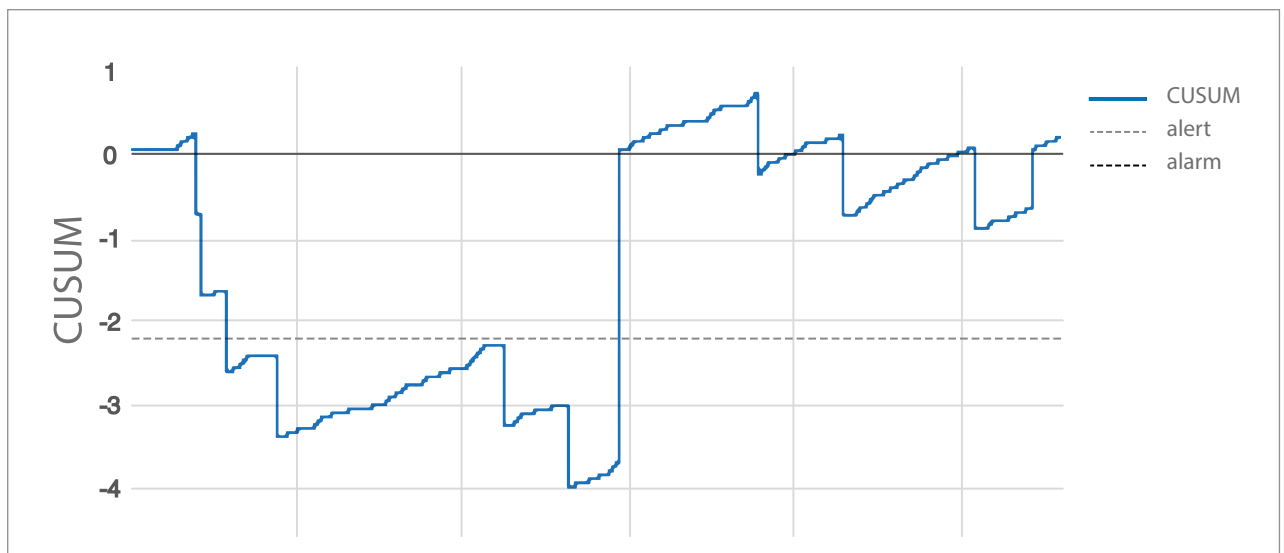
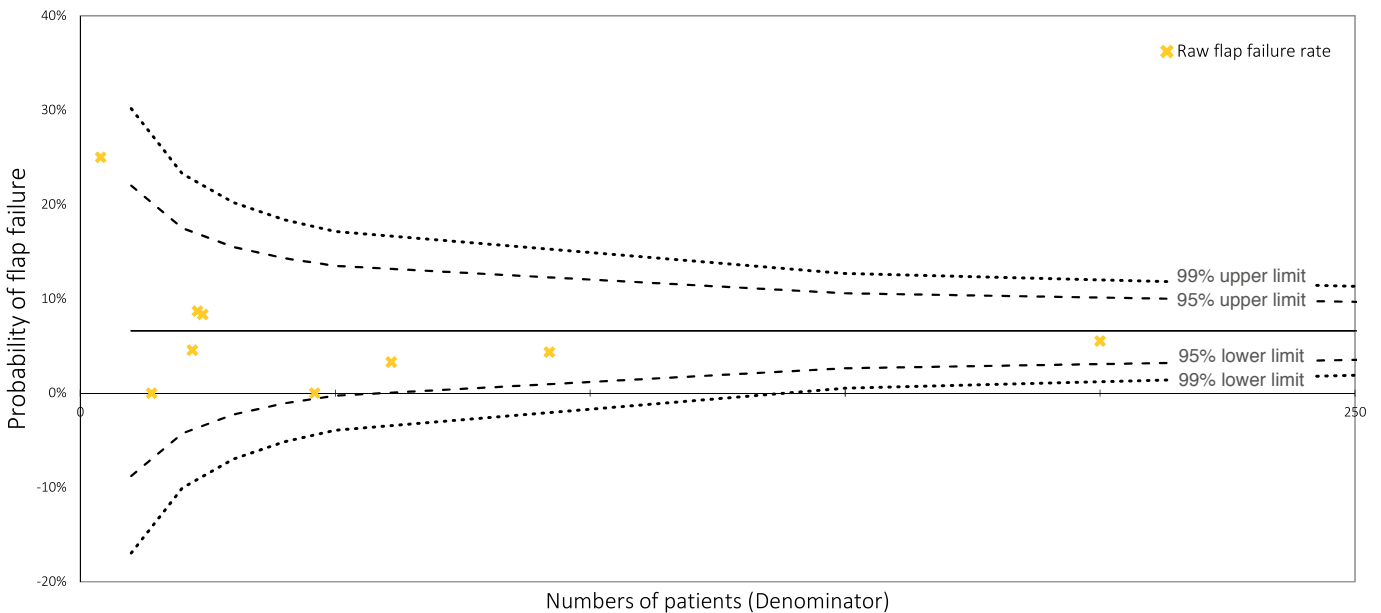
Free flap success

Free flap success is charted in the Cumulative Sum Chart. Raw data is used in an un-adjusted chart in which every flap success is awarded a 4.7% (mean failure rate) increment, and every failure a 95.3% (mean success

rate) decrement. A risk-adjustment algorithm (derived from a machine learning experiment of 8 units free flap data, >1500 cases) is applied to each episode and a weighting is given to the basic increment / decrement depending on the complexity of the case (Figures 8.14).

Figure 8.14

(a) Funnel plot showing raw flap failure rates by unit (top); (b) Example national CuSUM chart over 6 months activity (with a 50th case reset to 0) (bottom)



Discussion

With >1200 care episodes in the 1st audit year we anticipate QOMS will be in a strong position to re-develop models on a 1–2-year basis for all Oncology and Reconstruction metrics in a transparent manner that will accommodate for variations in regional case-mix, to hitherto possible in the pilot stages of risk-adjustment development.

Models allow adjustment for complexity of treatment that, we hope, we counter surgeons' reluctance to engage because of fear of unfair comparisons leading to risk-averse decision making.

With the exception of two hospitals, centres have <100 free flap cases thus far in QOMS OR registry and thus judgements about performance must wait until the confidence limits are narrower.

Funnel plots are suitable for presentation of risk adjusted data presented as cohorts over a set period of time, or pre-determined number of procedures. They do not facilitate ranking of performance which, in this context is a strength. They are however slow to signal significant diversion from expected performance.

Cumulative Sum (CuSUM) charts are a contemporaneous means of assessing performance, as a frequency of an event within bounds of variation, usually set at 2 or 3 standard deviations from an accepted mean frequency. We hope that aggregate and unit level data available on the Redcap dataset dashboards will encourage surgeons to scrutinise unit performance frequently. CuSUM charts have been applied to hospital level datasets signalling amongst other outcomes, excess in-hospital mortality. (26) To our understanding this is the 1st attempt at applying this process control methodology, indeed with machine-learning derived risk adjustment, that provides 'live dashboard' outcome reporting on free flap success at hospital level. This is an important step towards clinical governance processes available to reconstructive surgeons because it allows tracking of performance of an outcome of profound significance to the patient's recovery and use of hospital resources.

The UKNFR free flap registry currently captures data at unit level about volume of cases but is limited in scope by incomplete flap outcome data (11%) and re-operation data (>20%) which can surely obscure true knowledge

of flap failure rates in this high risk subgroup of patients (27) receiving free tissue transfer. Until flap outcomes are reported with >99% completeness and reported in a near contemporaneous manner that facilitates 'live audit' responding to deterioration in surgical performance by tracking patient outcomes is likely impossible. Further, reporting only raw outcomes without risk-adjustment, will also limit the ability to detect real change in quality of care, as opposed to baseline changes in patient risk profiles.

In QOMS we have embedded a risk-adjustment model, validated by 10x cross fold validation, on >1500 free flaps from 8 UK Head and Neck units, a similar case number to the entire 2019 UKNFR Head & Neck dataset, at the outset of this project. The champion model surpassing Bayesian methodology, uses more complex machine-learning approaches, is still 'fairly weak' in its ability to accurately predict outcome (it predicts just over 50% flap failure cases using patient & operation pre-operative data, see Table 7.15). However, we judge from our own experience of model building that the most likely determinants of free flap outcome reside not with the patient, but with the operating surgeons' technique and treatment plan and other, currently unmeasurable factors. While these features do not enter the model, the predictive ability of any free flap failure model will remain weak.

The American College of Surgeons National Surgical Quality Improvement Programme (ACS NSQIP) programme is also able to report impressive numbers of head and neck procedures with immediate reconstruction. Studies are published offering patient level risks that may inform patient consent but no embedded risk-adjustment model for flap failure yet exists. This programme does report unit level data on subscribed institutions but does not aspire to be a national endeavour in the way QOMS does within the NHS.

QOMS aims to be a patient-centred, clinician-led and delivered, national project. The relative presentation of unit-level data on national aggregate data should allow subjective judgements about quality of care that promises to drive improvement in clinical care.

Conclusion

QOMS Oncology and Reconstruction Audit, at an early stage, is demonstrating systems of a specialty led robust, fair, and sustainable system of quality governance.

Temporomandibular Joint

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TMJ Registry – current status, future developments, and its position within BAOMS QOMS

Authors: Saeed N, Ghaly G and Gerber B

Background

Temporomandibular joint disorders (TMDs) are common and can affect up to 30% of the population at some point in their lifetime. Despite primary care guidelines many patients are referred to secondary care Oral and Maxillofacial units but only a small proportion require surgical intervention. Excessive open TMJ surgery in the past has led to numerous patients with potential iatrogenic articular disease. The number of patients with true articular primary or secondary disease is small and this led to the formation of the British Association of TMJ Surgeons (BATS) which predated the current TMJ SSIG. This group developed the concept of all units offering conservative care and arthrocentesis but the notion of regional centralisation to allow better diagnosis, arthroscopy, and joint replacement for end stage disease. This small cohort of patients are probably best served by subspecialised surgeons concentrating on a high

volume of advanced TMJ work. In 2007 - this same group produced Guidelines for Temporomandibular Joint Replacement. (28) BATS worked with NICE to achieve guidance for practitioners and developed commissioning guidance. They also developed a voluntary database to support audit and comparative outcomes (see below) and provided expert/consultation support for further NICE approval. In 2014, the input of data into this national registry was included in the updated NICE guidance. At present there is no active registry for the management of TMDs. BATS has now been superseded by the TMJ SSIG.

It is estimated that up to 200 patients may require joint replacement surgery per year, but this can include patients in both the NHS and private sectors. Oral and Maxillofacial GIRFT data from April 2018 to March 2020 showed much smaller numbers of patients receiving TMJ replacement: 4 Oral and Maxillofacial units performing more than 12 patient cases and 8 units which completed less than 5 patient cases in 2 years. The 4 units did most of all TMJ replacements in the 2 years considered (*Table 9.1*). Clearly units doing higher volumes would be better and data to support this is required. This is supported in principle by both NICE and GIRFT.

TMJ surgery and TMJ replacement surgery by NHS England region from April 2018 to March 2020

Table 9.1

Region	Number of units	TMJ surgery excluding joint replacement	TMJ replacement	TMJ replacements by unit
Northeast	18	483	1	1
Southeast	17	789	49	1,48
Southwest	14	609	16	1,7,8
Northwest	17	414	35	1,10,24
Midlands	19	933	83	3,27,53
London	13	560	28	3,3,5,6,11
East of England	12	383	0	N/A
Total TMJ replacements in England			212	

Historical data bases

The self-established BATS group of surgeons who developed guidelines for TMJ replacement developed a national TMJ registry. This was a Snaps Survey data

base funded by a grant from the British Association of Oral Maxillofacial Surgery. This initial data base helped establish TMJ replacement as a successful procedure in the appropriate patient, when performed in appropriate centres and aided the development of NICE guidance.

The contributions in particular of Bernie Speculand and Andrew Sidebottom should be acknowledged. Baseline data was published in 2014 in the BJOMS. (29) This analysed data from 1994 to 2012 and identified 16 surgeons who had contributed data from 11 different centres. There were 402 patient records of 557 TMJ replacements. The data supported the benefits of TMJ replacement surgery. The main diagnoses that resulted in total joint replacement were osteoarthritis, failed operation, ankylosis, and seronegative arthritis. Preoperatively, the median (IQR) maximal incisal opening was 20 (15–26) mm (mean 20) and the median pain scores on the visual analogue scale (VAS 0–10) were 8 for both joints. The median (IQR) baseline dietary score (liquid 0 – solid 10) was 4 (3–6). A total of 173 (43%) patients had had one or more open procedure(s) before total replacement, 177 (44%) had not had open operation, and 52 (13%) had no data entered. The 3 primary systems used were the TMJ Concepts System (Ventura, USA), the Biomet System (Biomet/Lorenz Microfixation, Jacksonville, USA), and the Christensen System (TMJ Implants, Golden, USA). The median (IQR) duration of inpatient stay was 3 (2–4) days (mean 3). Follow-up data will be collected to assess patient recorded outcome measures (PROM) and objective measurements of total joint replacements in the UK from 1994 onwards

Elledge et al in 2017 published the one-year outcome data in the BJOMS. (30) This included patients in the registry up to 2014 and revealed 592 baseline data records and 252 one-year records. This again confirmed good outcomes. A total of 252 one-year outcome records were available. Key outcomes were median (IQR) improvements in interincisal distance of 9 (4–15) mm ($p < 0.001$) and worst-sided pain score of 6 (4–8) ($p < 0.001$). Pain scores improved or remained static at one year in all but 3 (2%) patients. There was a significant improvement in the proportion of patients who reported a good, very good, or outstanding quality of life at one year (38% at baseline to 87% at one year; $p < 0.001$). While outcome reports from single centres for alloplastic TMJ replacements have already been published in the United Kingdom, this is the first dedicated national database in this country that will yield valuable longitudinal follow-up data. Outcomes were comparable with smaller published series and showed improvements in pain, dietary intake, quality of life, and function, with few outliers. The database has recently moved to a new software system, and we hope to publish three-year and five-year outcomes in due course.

Issues with funding of the Snaps Survey database led to a new collaboration and funding request with NFORC and

BAOMS. A decision was made to set up a new database with Dendrite. Funding was secured through NFORC, and the data input variables were to remain unchanged with baseline, 6-week post-surgery data and annual data. This would therefore continue to collect objective data (mouth opening, complications), subjective data (pain and diet scores) and PROMS on quality of life. It was planned to migrate data from the original database. This required substantial effort. The database was a web-based portal and ran from 2014/15 to around 2019. Dendrite costs for analysing or reporting the data were apparently not included in initial agreements and further funding was therefore required for this. Data entry was sporadic and sadly poor such that NFORC could not justify the ongoing costs and the database was closed.

At this present time, the data has been stored securely by NFORC and the plan is for BATS representatives to provide a demographic review and narrative discussion.

The database comprises the following tables:

1. Pre-Procedure (902 entries with 32 fields per entry)
2. Sub-Procedure (242 entries with 14 fields per entry)
3. Post-Procedure (904 entries with 6 fields per entry)
4. Follow-up (870 entries with 37 fields per entry)

There are, however, gaps in the data. In terms of patients - they are entered as unilateral or bilateral TMJ procedures if done in a single episode. If a patient has a unilateral joint followed by the contralateral side in the future these are entered as separate entries. There are over 998 records in this database. Data migration of the original data was attempted but was unfortunately problematic to the extent that corruption of the data may have occurred.

Current situation

There is no national registry for TMJ replacement at present. In conjunction with NFORC a new data base within a Redcap portal has been devised. The data entry variables have been reviewed by a small working group of surgeons led by Mr Ghaly Ghaly (Mr Nadeem Saeed, Miss Barbara Gerber, and Mr Martin Dodd), the data entry modified and simplified. The database is still very lengthy and will require significant input by motivated individuals or specialised specific data input personnel. This remains the greatest barrier to data collection. The new specialty SSIG Lead will need to review the current piloted plan and form. Entry onto a national TMJ registry was recommended in the NICE guidance 2014 and so units must show some form of audit if challenged and the introduction of a new database is a potential priority.

The major ongoing problem has been the participation of surgeons and units. The NCIP portal can collect data for individuals and provide this data for appraisal and education using already collected HES data. A simplified

database based on similar variables to the orthopaedic joint registries could also be considered. Whichever database is chosen it should be aligned to the BAOMS QOMS project.

Discussion / future plans

1. Registries for rare disease in the Maxillofacial region:

a. The BAOMS QOMS team (after consultation with Salivary Gland Cancer UK and patient representatives) have developed a multidisciplinary Salivary Gland Cancer Registry with the input from a patient-public advisory group. This prospective registry will be rolled out to the BAOMS QOMS participating units and all Head and Neck cancer teams/clinicians in the UK are welcome to access and contribute data.

b. The BAOMS QOMS team is working with multidisciplinary colleagues to develop a UK-wide registry for the registration of patients with benign odontogenic tumours of the jaw. This prospective consented registry is working towards a network of regional/national collaborative multidisciplinary case review and discussion to record treatment options utilised and patient outcomes.

2. Patient specific implant registry for maxillofacial reconstruction – a working group formed of BAOMS QOMS representatives, BAOMS Reconstruction SSIG

Lead and Deputy Lead, and clinicians with academic/service development interest in this subject has been formed to develop a registry for patient specific mandibular osteosynthesis plates utilised in the composite reconstruction of segmental mandibular defects. This registry aims to evaluate the safety, efficacy and treatment outcomes for patient specific implants utilised in this context, which has become increasingly common over the last decade.

3. Following a period of extensive collaborative consultation between the BAOMS QOMS Orthognathic Surgery representative (AAyoub & F Puglia) and the British Orthodontic Society representatives (S Cunningham & H Travess) to develop the Orthognathic Surgery Patient-Reported Outcomes Measures (PROMs) questionnaire, we will be successful in improving multidisciplinary data contribution to this subgroup of patients. The PROMs which have been developed will form an important component of the evaluation of the value and impact of orthognathic surgery for our patients, which will hopefully provide clear reported data of the patient perceived benefits of orthognathic surgery and the impact the treatment provided and have on their lives.

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Appendix

CuSUM charts

The different types of classification errors can be summarized in a confusion matrix, as follows:

		Predicted Class Label	
		Negative	Positive
True Class Label	Negative	TN	FP
	Positive	FN	TP

Where:

- TP = # true positives, i.e., the number of examples (patients) of the positive class which were correctly predicted as positives,
- FP = # false positives, i.e., the number of examples of the negative class which were wrongly predicted as positives,
- TN = # true negatives, i.e., the number of examples of the negative class which were correctly predicted as negatives,
- FN = # false negatives, i.e., the number of examples of the positive class which were wrongly predicted as negatives.

Note that $TP + FP + FN + TN = n$ (where n is the number of examples (patients)).

The following measures of Precision, Recall and F1-score are defined based on the above confusion matrix notation:

- Precision = $TP / (TP + FP)$
- Recall = $TP / (TP + FN)$
- F1-score = $(2 \times \text{Precision} \times \text{Recall}) / (\text{Precision} + \text{Recall})$

The F1 score is the harmonic mean between the precision and recall. It is important to maximise the F1 score, to account for the trade-off between Precision and Recall (since an increase in one of these two measures usually leads to a decrease in the other).

Note that the calculations of Precision, Recall and F1-score require the specification of what are the positive and negative classes. In this work, we use the common approach of first computing these measures and then, for each measure, we compute the average over those two values, producing the so-called macro averages of Precision, macro Recall and macro F1-scores. Note that

these macro averages consider the performances in the predictions of both classes as equally important. We consider this is a more informative measure than the micro averages of Precision, Recall and F1-scores, which are the weighted averages of these measures (weighted by the numbers of examples in each class), because the values of those weighted micro averages would be overwhelmingly dominated by the performance in the majority class, due to the large class imbalance in our dataset. Hence, we often report the macro averages of Precision, Recall and F1-score.

A Receiver Operating Characteristic (ROC) curve is a plot of the True Positive Rate (TPR) versus the False Positive Rate (FPR), where:

- True Positive Rate (also called Sensitivity or Recall) = $TP / (TP + FN)$, i.e., the number of True Positives divided by the total number of positives.
- False positive rate = $FP / (FP + TN)$, i.e., the number of False Positives divided by the total number of negatives, which is also equal to $1 - \text{Specificity}$, where $\text{Specificity} = TN / (FP + TN)$.

The ROC curve is produced by varying the value of a classification threshold on the probability of the positive class predicted for each example, so that different values of that threshold generate different points (TPR and FPR values) on the curve; and the area under that curve is a popular measure of predictive performance. It is a ranking method. The Area under the Curve (or C statistic) is the probability that the diagnostic test will assign a higher probability to a positive instance of the event to the probability assigned to an event with a negative instance.

The Brier score is a quadratic scoring rule, where the squared differences between actual binary outcomes Y and predictions p are calculated: $(Y - p)^2$. We can also write this similar to the logarithmic score: $Y \cdot (1 - p)^2 + (1 - Y) \cdot p^2$. The Brier score for a model can range from 0 for a perfect model to 0.25 for a non-informative model with a 50% incidence of the outcome. When the outcome incidence is lower, the maximum score for a non-informative model is lower. The scaled Brier score is adjusted to represent the discrimination performance of a score on a range between 0% and 100%.

CuSUM charts were constructed as described by Rasmussen et al. (26) The predicted probabilities were used to give patient-specific risks to modify the CUSUM chart. The risk-adjusted CUSUM chart plots the function:

$$X_t = \max(0, X_{t-1} + W_t), t = 1, 2, 3, \dots$$

Where W_t is a weight assigned to each value of t . In this study, the risk-adjusted CUSUM charts were updated on a patient-to-patient basis, i.e., each value of t corresponds to a new admitted patient. Consequently, the weights W_t are given by

$$W_t = Y_t \log(RA) - \log(1 - p_t + R p_t)$$

Where Y_t is the outcome of patient t (free flap failure within 30 days of operation date yes/no) and p_t is the expected probability of the outcome estimated from a prediction model based on data from a reference period. Finally, $RA > 1$ is a specified Odds Ratio (OR) increase in the outcome rate, as compared to the reference period, that the risk-adjusted CUSUM chart is set to detect, and we set it at 2 (or twice the expected rate). We set the weight W_t as positive if the patient did not have the outcome, and negative if they did. The absolute value of the weight was large if the outcome is unexpected. Thus, in this process, if more patients had free tissue failure than predicted, the CUSUM function would decrease.

Further reading

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