**ENT Quality Improvement Program as a tool to improve the collection of morbidity and mortality data: a multisite audit carried out over 6 months**

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**ABSTRACT**

**Objective** This project aims to assess the role of a standardised process of data collection to improve morbidity and mortality data across the region.

**Design** Six hospitals within the North West (UK) were recruited and adopted the ENT Quality Improvement Program (QIP) into their daily practice. Monthly anonymous data were sent back to the reviewer for trend analysis.

**Outcome measures** Four outcome measures were defined: (1) number of cases recorded within the region each month; (2) assessment of the severity of cases and trends; (3) assessment of action plans reviewing any changes in practice made as a result of using this tool; (4) long-term use of the tool and qualitative feedback from units.

**Results** 162 patients over the 6 months were included with 180 case discussions. 170 of these were morbidities and 10 were mortalities. Mortality was more frequent in patients with a diagnosis of head and neck cancer. Of the 162 patients, 133 encountered postoperative complications. Post-tonsillectomy (62/133 47%) and post-thyroid surgery (19/133 14%) complications were the most frequently encountered. 66% of the complications were low grade with 18% requiring management under general anaesthetic. Actions plans included four policy reviews with the introduction of three new policies. All sites found the tool user-friendly and are continuing to use it beyond the data collection period.

**Conclusions** The ENT QIP has been found to be a simple, user-friendly tool which has improved the quality of data over the six sites and resulted in improvements in practice. Implementation of the tool allows clinicians to critically appraise their practice and to reflect as well as to demonstrate how complications have resulted in change.

**BACKGROUND**

Morbidity and mortality (M+M) analysis forms an integral part of surgical practice enabling clinicians of all grades to reflect on their outcomes and complications. In accordance with Good Surgical Practice and guidance produced in 2015 by the Royal College of Surgeons (RCS), all surgeons should regularly participate in morbidity and mortality discussions. The guidance further describes the frequency of these meetings and the relevant issues affecting the practice of the department. The four key areas for discussion of each case which are specified within this guidance include:

1. Case discussion.
2. Grading of severity.
3. Justification as per the national confidential enquiry into patient outcome and death (NCEPOD).
4. Action plans to prevent reoccurrence.

Despite advancing surgical quality standards, data reporting and adverse incident review have been highlighted as areas for development. Often, outcomes of such discussions are taken with a degree of distrust culminating from questions as to the integrity of the data presented. The fundamental flaw within most departments appears to lie with the haphazard retrospective method of data review performed frequently by inexperienced trainees with little reference to complication rates or prior occurrences due to junior staff rotating throughout the region.

Quality improvement projects have been shown to be successful in improving the quality of such data collection. The American College of Surgeons National Quality Improvement Program (ACS-NSQIP) acts as a prime example of a peer-reviewed prospective database tool for data collection which has resulted in standardisation of M+M endpoints, reliable data and improvements in surgical care.

As a large-scale QIP, the ACS-NSQIP concept has been downsized and used within various guises with successful implementation. In 2013, McVeigh et al published their study in which they used a similar format to the ACS-NSQIP. Using a prospective database to collect their M+M data, they found that using such a tool provides significantly more accurate assessment of M+M data which aided in surgical performance indicators and case-mix funding. In 2013, a UK model was instigated within a tertiary hepatobiliary unit.
A prospective database tool was used to analyse complications extrapolating the concepts of the ACS-NSQIP project. The favourable outcomes of implementing the model over a 6-month period highlighted a significant improvement in the quality of the data collected and also, more interestingly, identified protocol changes and a statistically significant reduction in their complication rate post-pancreatic surgery.7

AIM AND OBJECTIVES
The ENT QIP is a simple tool that enables users to quickly assess, grade and review cases/complications prospectively with the overall aim of improving collection of morbidity and mortality data to help to identify areas for improvement.

The aim of this project was to assess the role of a standardised process to improve M+M data collection throughout six hospitals in North West England and assess the long-term ease of use of such a tool.

Following its implementation four primary outcome measures were reviewed:
1. Number of cases recorded within the region each month.
2. Assessment of the severity of cases and trends.
3. Assessment of action plans reviewing any changes in practice made as a result of using this tool.
4. Long-term use of the tool and qualitative feedback from units.

METHODS
Six hospitals within the region were recruited to the study with the help of the North West Research Collaborative. The ENT QIP toolkit was used to replace existing methods of collection of M+M data at each site. A representative was chosen from each site to ensure comprehensive data collection and timely dissemination of data. Following each month’s audit meeting and discussion of the cases with a consultant, anonymised data were sent to the central data collector. Data were reviewed at 6 months (August 2017–January 2018) to assess outcomes 1–3 with qualitative surveys and questionnaires sent out at 6 and 12 months following its implementation to assess outcome 4.

Data collection and ethical considerations
Data collection was extrapolated into an Excel spreadsheet tool which was securely saved on trust computers with appropriate patient confidentiality restrictions.

The lead representative encouraged daily data collection in a prospective manner to limit loss or missed data. Patient confidentiality was maintained by ensuring patient-identifiable data were not transferred to the central reviewer.

For the purpose of anonymity, hospital site-specific data have been anonymised.

Ethical approval was not required prior to commencement of this study.

RESULTS
Six hospitals introduced the ENT QIP into their daily practice within the North West Deanery (Greater Manchester and Mersey) with 100% compliance to the RCS 2015 guidance over the 6-month period.

Outcome 1: number of case discussions each month
A total of six hospitals yielded an aggregate of 162 patients that were discussed over the 6-month period. In these patients, there were 170 (94%) morbidities with some patients suffering multiple complications and 10 mortalities (6%) (total 180 case discussions) (see online supplementary appendix table 1 Basic demographic data).

The number of cases varied between sites but similar numbers were seen on a month-by-month basis.

Of the 180 case discussions, 133 were postoperative and 47 occurred after being admitted under ENT firms.

In the postoperative group, the highest frequency occurred post-tonsillectomy at 47% (62/133) followed by thyroidectomy at 14% (19/133) (see online supplementary appendix table 2).

Of those requiring emergency department admissions, patients with epistaxis were the most frequent to encounter complications 15/47 (26%) (see online supplementary appendix table 3).

Outcome 2: assessment of severity of cases and trends
Cases were assessed using the Clavian-Dindo grading system.8 A total of 120 cases (66%) were graded 1 or 2 requiring pharmacological treatment only (see online supplementary appendix table 4). Fourteen (8%) cases required management without general anaesthetic and 32 (18%) required a general anaesthetic. Four cases required escalation of care and a total of 10 patients died.

Of all patients who went to theatre, bleeding was the primary cause in 24/32 (75%); 20 of these were postoperative complications.

Of the complications presenting post-tonsillectomy, 74% were managed medically and 18% required treatment under general anaesthetic.

Complications following thyroid surgery were the second most frequent. Of these 19 complications, 15 (79%) were managed medically with only four patients returning to theatre (21%). One hundred per cent of patients returning to theatre did so as the result of haemorrhage.

Head and neck patients with a confirmed diagnosis of malignancy made up 41 of the 180 cases (44%). Separating these patients from the benign pathology, we see that 17% of these included a mortality, in comparison with the remaining cases (n=139) in which mortality made up only 2% of the case discussions (see online supplementary appendix table 4).

Of the 10 patients who died, 6 occurred following an emergency admission. Three patients with a late presentation of undiagnosed advanced head and neck cancer developed pneumonia, one of whom also had concomitant urosepsis. One died as a result of a penetrating neck
trauma, and the final two cases were as a result of severe meningitis secondary to an acute otitis media.

The four perioperative deaths include one trans-nasal skull base biopsy who developed major haemorrhage, one emergency surgical tracheostomy for advanced oropharyngeal cancer who developed chest sepsis, one parotidectomy and neck dissection who developed postoperative chest sepsis, and finally a head and neck cancer patient who underwent a percutaneous endoscopic gastrostomy insertion who developed postoperative chest sepsis.

Of all of the deaths, seven patients had an advanced head and neck cancer diagnosis with chest sepsis being the modal cause of death in 6/10 (60%).

Outcome 3: assessment of action plans and any subsequent changes in practice
In a majority of cases, 161/180 (89%) action plans involved tracking and monitoring rather than changes being introduced. In the remaining 19 cases, action plans varied from teaching to starting new policies (see online supplementary appendix table 5).

Outcome 4: long-term use of the tool and qualitative feedback from units
Following the 6-month data collection, a questionnaire was forwarded to departments specifically for registrars using the tool and the relevant audit leads. A five-point Likert scale was used to assess each question with the scale ranging from strongly disagree to strongly agree (see online supplementary appendix 2).

All sites found the tool easy to introduce locally and the tool itself was easy and quick to use (Q1–3). One site had data storage issues with no access to a shared drive resulting in hard copy records being used and secured within the doctors’ office on the ward. All sites felt that the ENT QIP improved the quality of data collected and presented, encouraged critical reflection and has resulted in changes in practice (Q5–7). Some sites identified teaching requirements (Q8 and 13) and most (5/6) registrars would universally recommend the use of the project within their next placement.

Consultants universally agreed that the ENT QIP improved the quality of data collected and presented. The majority (5/6) felt that it promoted critical thinking and has resulted in changes/improvements in practice (Q10–12). Similarly, 5/6 of the consultants were happy for the tool to continue to be used. One consultant was undecided and asked for certain changes to the grading of complications (not discussed within this article). Following these changes, they are now happy to continue to use the tool. One consultant felt that it had not significantly resulted in a change in their practice as they already had a robust system in place for assessing and analysing complications.

Following a further 6-month period, a follow-up email was sent to all departments to see if they are planning on continuing the use of the tool which 100% responded positively.

DISCUSSION
Impact of the project
The data have highlighted some important trends.

First, we see an even distribution of case discussions throughout the region with similar monthly complication numbers. This reassuringly demonstrates an absence of peaks and troughs which might be expected during change over of staff particularly when comparing the August to January data.

Second, from our results, we can extrapolate that complications following tonsil surgery and thyroid surgery were the most frequently encountered; however, the majority of these (75% and 79%) were medically managed. This trend can assist local services plan their provision of care. This highlights the significance of appropriate training of junior staff to enable recognition of complications which in the majority of cases can be managed medically on a ward-based level. In light of having identified the majority of the complications are low grade, when severe complications do occur, a significant proportion of these are due to haemorrhage (75%). This further highlights the requirement during staff induction periods for appropriate guidance on escalation of care to seniors.

The next trend identified is the relationship between the mortality of head and neck patients being statistically higher than non–head and neck patients (17% of cases compared with 2%). With a higher associated mortality, it is vital that head and neck centres ensure that all staff are appropriately trained in the management of late-presenting head and neck cancer to provide holistic care.

Of the three non–head and neck mortalities, 2/3 (66%) were as a result of complication of acute otitis media (AOM). AOM is a common presentation to the ENT department and an even more common presentation within the community. Despite reported mortality from complications of AOM being low (globally 21 000 cases a year/33 cases per million people),9 our identification of two such sequelae highlights the implication of ensuring early recognition of them. This should be used to evidence the requirement for appropriate staff and patient education within the community for red flag meningitic signs that need to be watched out for.

Finally, we see that action plans and change can occur as a result of a standardised process such as this. As a result of this project, numerous teaching sessions and educational opportunities were held as well as policy changes, one of which resulted in a publication looking at the regional management of postoperative hypocalcaemia. This demonstrates that such data can be used to inform changes in practice as well as focus ideas for research and development.

Controversy
On review of the cases, we identified some areas of controversy within the patients admitted via the emergency department. Four cases graded as IIIb (requiring treatment under general anaesthetic) were epistaxis patients with ‘failed medical therapy’. All four patients had been
packed, de-packed and subsequently required repacking with a resultant surgical approach being taken. It is recognised that though surgical management of an epistaxis is not itself a complication, a patient requiring repacking and surgery could be deemed to be. This is an area of controversy, and even within our six units, we recognise that site leads may differ in their classification of this. We as authors cannot comment on the specific details of each case and as such have included the details as provided from each site. It is very difficult to standardise even regionally what classifies as a complication secondary to an emergency admission under ENT. Certainly, a patient admitted in whom a hospital-acquired infection or other similar event occurs would be included, but we are guided by the individual sites as to their documented adverse events. Highlighting this identifies further that standardisation of epistaxis management is key and that current guidance on epistaxis management should be reviewed with an aim to improve the care our epistaxis patients receive.10 11

**Process of quality improvement**

Quality improvement tools have been shown to lead to improved outcomes and reduced costs when applied and used correctly.3

We propose that standardising data collection in this way throughout the region will lead to a universal improvement in the quality of our M+M data.

Our questionnaires have shown that, as a tool, it has been simple to set up and use, and has resulted in clear improvements in practice. All of the sites have continued to use the tool beyond the data analysis review providing further evidence to the tool’s ease of use and the positive effect it has had on each department’s M+M process. All surgeons need to demonstrate review of their complications/cases, and this tool enables a user-friendly interface to perform this task. Implementation of the tool allows clinicians to critically appraise their practice and to reflect as well as to demonstrate how complications have resulted in change. This can be used as a tool should complications recur to assess where improvements ought to have been made as well as linking into other tools such as incident forms and underpinning RCA (root cause analysis).

**Limitations**

One key limitation is in the accuracy and completeness of the data recorded. It is hoped that the encouragement of prospective data collection should have resulted in a more complete data set. Certainly, the feedback for the teams involved is positive in this regard and reassuring that the quality of their M+M data has improved. Ensuring that medical staff remain engaged in the process is key and local audit leads must take responsibility for ensuring the accuracy of their M+M data. Qualitative feedback reveals that the QIP has improved the quality in this regard, but for this to be continued, staff locally will need to ensure a lead is selected as juniors rotate around the region.

Discussion of complication rates is beyond the scope of this article which set out to assess the complication numbers and use of a QIP tool in improving data capture and analysis. We acknowledge that we are unable to comment on complication rates as we have no baseline numbers. As a result, sites have not been directly compared as throughput of patients varies significantly.

Out-of-hours cross-coverage for ENT patients commonly occurs over multiple sites with patients having easy access to various ENT firms across the region. The impact of this results in postoperative complications not necessarily presenting at their base site. We acknowledge it to be a limitation, and this further explains why true complication ‘rates’ are difficult to obtain. For the purpose of this study, any regional patient presenting to one of the six sites has been included in that site’s data as we are looking at overall regional complication rates rather than site-specific information. Out-of-region postoperative patients have been excluded. One way of improving data collection, in this regard, would be to develop an online regional platform or database for data to be collected and analysed, resulting in operating sites being made aware of their complications should they present elsewhere. This is currently a work in progress for the ENT QIP tool.

**CONCLUSIONS**

The ENT QIP has been found to be a simple, user-friendly tool which has improved the quality of M+M data over the six sites. It has highlighted topics requiring future research, namely, post-tonsillectomy, post-thyroid and epistaxis management. It has demonstrated that even though complication numbers are low, as a specialty, ENT have a large number of patients that require treatment under general anaesthetic with bleeding being a commonly encountered complication. As a result, the importance of appropriately trained ENT covering staff has been discussed.

We have highlighted the importance of optimum ENT junior doctor level cover and also the importance of early recognition of complications particularly within head and neck centres which should include the delivery of training to all members of staff working in these environments. The tool has also drawn attention to the significance of training in community-based care and patient education for patients with AOM to ensure early recognition of red flag signs.

It is hoped that the positive experience of the six sites will disseminate throughout the region leading to a standardised process of morbidity and mortality analysis which can only act to improve the quality of the data collected as more users become aware of the QIP process. This will also help in the arsenal of improving patient quality of care and ensuring good medical practice as prescribed by the GMC. The ENT QIP tool is a work in progress and is constantly evolving according to the feedback provided from its users. It is hoped in the next 12 months to create an online platform which will capture all complications.
via a confidential database enabling easier data entry as well as data review.

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Contributors RE designed, organised and implemented the study regionally. RE performed data collections, analysis and interpretation as well as writing the paper. RA aided in regional implementation, assisted in data analysis and in drafting the paper. SK and BNK aided in the regional implementation, analysis of data and editorial review of the paper.

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