Identifying and investigating apparent variation in care based on continuous outcome monitoring

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The role of continuous outcome monitoring

Hospital outcome data is frequently reported in aggregated form in a retrospective, cross-sectional analysis (typically a 12-month period). Data may then be used to determine if the number of observed adverse outcomes (e.g. patient deaths or complications after surgery) in the chosen period is higher (or lower) than expected based on the average for all hospitals.

Data is reported back to hospitals by the NELA team in this format using a funnel plot (see figure 1). Here hospitals risk-adjusted performance is compared with deviations from the average.

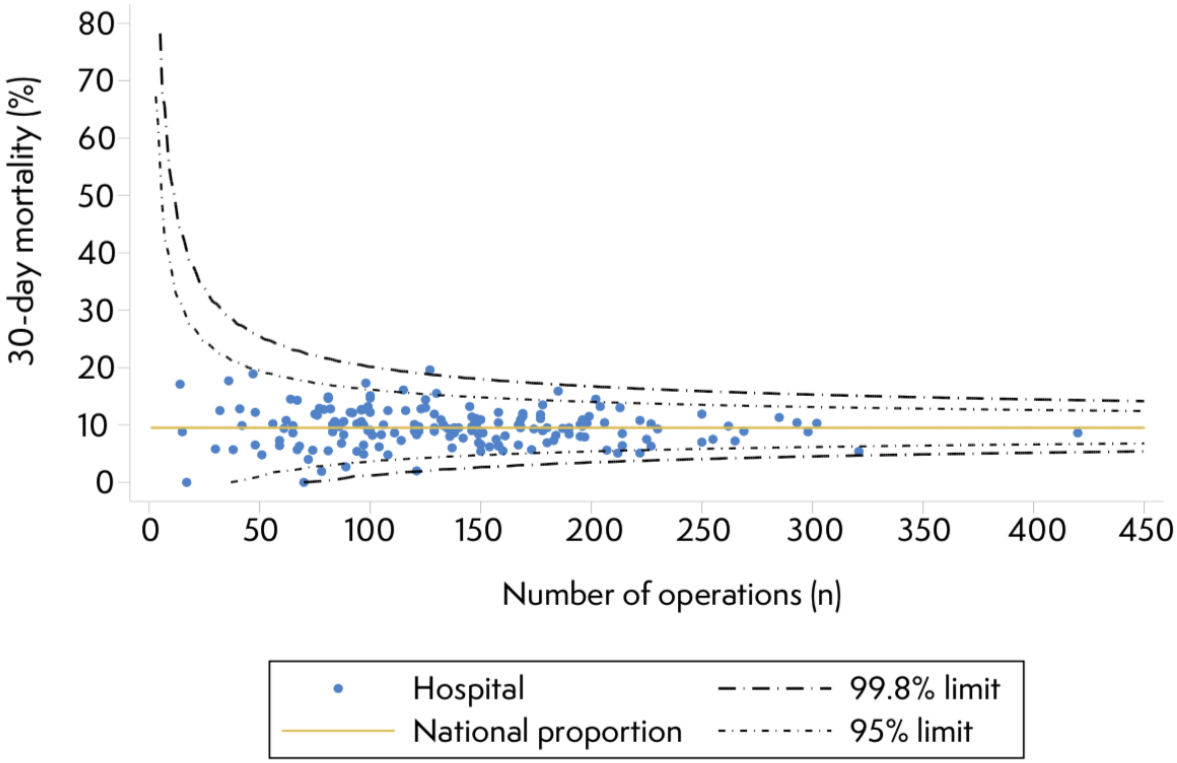

Figure 1: Funnel plot of risk-adjusted Office of National Statistics 30-day mortality rates from the Fourth NELA patient report[1]

Continuous outcome monitoring charts, such as the variable life-adjusted display (VLAD) and exponentially-weighted moving average (EWMA) charts provide information on a more continual basis, allowing earlier identification of good or bad trends in outcomes. They are similar to other continuous charts such as run charts and statistical process control charts (SPCC) which support the identification of 'normal cause' and 'special cause' variation.

Normal cause variation is fluctuation over time considered normal or intrinsic to a process. Many continuous monitoring charts have been adopted from the manufacturing industry and were developed to identify problems in the manufacturing of goods, such as the size or shape of a part.

Taking fluid infusion pumps as an example. A predefined tolerance level around the accuracy of infusion rate is decided during the manufacturing process. The pump is produced so that the volume of fluid delivered is equal to that set by the user. If this tolerance (or control limit) was +/- 1ml we would expect that if we took 100 pumps and delivered fluid through them all at a rate of 100mls/hour, the volume delivered would be between 99 and 101mls for all 100 pumps (normal cause variation). However, if there was a sudden problem with manufacturing that meant pumps delivered <99mls or >101mls then the control limits would be crossed for that time period and special cause variation is identified.

Crossing a control limit (considered to signify 'special cause variation') on the EWMA does not necessarily mean a hospital will be identified as an outlier on cross-sectional analysis, but it does signal a potential underlying increase (or decrease) in adverse outcomes that requires investigation.

The introduction of continuous risk-adjusted outcome monitoring aims to reflect the dynamic nature of healthcare. Outcomes fluctuate over time, be it due to the introduction of new care pathways, seasonality or other changes in hospital structures or processes. Investigation of significant deviations may lead to better understanding of problems and allow changes to be put in place earlier to improve patient care.

Special cause variation may not always be negative (poor outcomes). Control limits may also be crossed on the positive side (indicating improved outcomes compared to expected). EWMA charts support the monitoring of quality improvement (QI) initiatives and may support clinicians to identify whether QI has led to a positive change in outcomes.

When should an investigation be carried out and what should be done if there is a change in the trend of an outcome is a difficult question to answer. Waiting until a control limit is crossed or investigating a possible deviation sooner are both options. Investigations prior to crossing a control limit may increase the workload of hospital teams. Such deviations may only reflect 'statistical noise' or common cause variation. However, investigating a clear and marked deviation from the previous course even before control limits are crossed may lead to important findings and learning that can benefit the care of future patients. The decision of when to investigate may for example depend upon local resources and the availability of staff to review case records and databases. However, once control limits are crossed there is a statistical signal that performance has deviated beyond the prespecified limits. This is something that should alert hospital teams to investigate possible causes. Being identified as an outlying hospital on cross-sectional analysis should also stimulate an investigation into possible causes.

Once a control limit has been crossed, **we recommend an internal audit of all inpatient deaths after emergency laparotomy that occurred in the six months before the control limit was crossed, or of at least the last ten deaths after emergency laparotomy (whichever method suggests the larger number of deaths to be reviewed).** We suggest using the 'pyramid' approach detailed below as a basis for this audit (see figure 1). The template provided at the end of this document may help with the audit process.

EWMA charts have been implemented to support local sites in identifying a change in outcomes earlier than with annual reporting. They are viewed as a formative process to monitor the impact

of QI and help identify trends in adverse outcomes so that changes can be put in place earlier to improve patient care.

The pyramid model considers five tiers, from the wide base (frequent cause of variation) to the narrow tip (less common cause of variation).

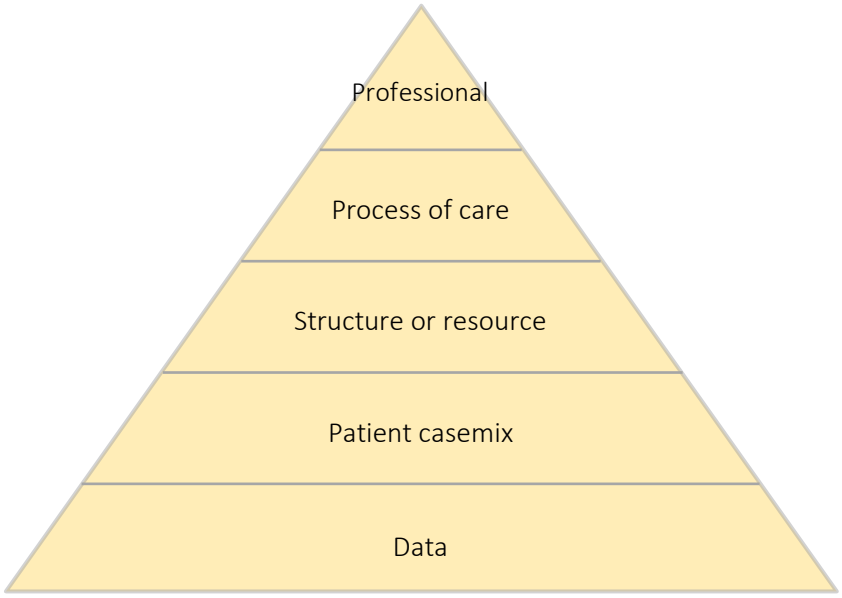

Figure 1: Pyramid model for investigating outcomes (presented by Mohammed et al[6])

Tiers of investigation of an apparent change in outcomes – the pyramid model

The following information has been adapted from Duckett et al.[2]

Data

Aims to identify data quality issues (e.g. coding accuracy, reliability of medical notes, definitions and completeness).

Typical investigation questions

- Are the data inputted correctly?
- Are patient risk factors used to calculate expected risk in the model coded appropriately?
- Has there been a change in data collection practices? (e.g. a change in people collecting data, less experienced people collecting the data)
- Is clinical documentation clear, complete and consistent?

Patient casemix

Differences in casemix are accounted for in the risk-adjustment process as much as possible given the data available. The EWMA chart is produced using the published NELA risk-adjustment model.[3] Whilst this model had good discrimination (C-statistic 0.863, 95% CI 0.858-0.867) and good

calibration when developed and internally validated, it is possible that some residual confounding might remain.

Questions to consider

- Are there factors peculiar to this hospital not taken into account in the risk adjustment?
- Has the pattern of patients admitted and operated on in this hospital changed (in a way not taken into account in risk adjustment)?

Structure or resource

This part of the investigation considers the availability of beds, staff, and medical equipment, together with institutional processes. It seeks to identify a change in the way the hospital is structured.

- Has there been a change in the distribution of patients in the hospital, with more patients spread through the hospital rather than concentrated in a particular unit?
- Has there been a change in referral and admission practice to level 2 and level 3 care areas?
- Have specialist emergency laparotomy services been established that may have led to improved outcomes?[4,5]

Process of care

Processes of care refer to the medical, nursing and allied health professional treatments of patients. It also includes clinical pathways, patient admission and hospital discharge policies. Process measures are reported back to hospitals by the NELA team on a quarterly basis. Dashboards are also available in the NELA webtool that allow hospitals to monitor several processes, such as: interval from decision to arrival in theatre time, documentation of risk, presence of a consultant surgeon and anaesthetist in theatre, and direct admission to critical care following surgery.

- Has there been a change in the care pathway being followed?
- Have new treatment guidelines been introduced?

Professional

This step of the investigation process seeks to identify if there has been a change in the practice or treatment methods of the teams involved in the care of patients.

- Has there been a change in staffing for treatment of patients? Have additional staff being recruited to fulfil specialist roles?[4,5]
- Has a key staff member gained additional training and introduced a new method that has led to improved outcomes?

Concluding statement

By working through each of the suggested steps above it should be possible to identify where changes may have led to improved or deteriorating outcomes. We wish to emphasise again that the process of investigation should not seek to apportion blame to individuals or the institution as a whole. The purpose of the pyramid model is to highlight the wide variety of causes that impact on outcomes before reaching the narrow ‘professional’ level at the tip.

If a clear explanation for a change in outcomes has been found at lower levels of the pyramid it may not be necessary to continue the investigation to the levels above. However, if changes are put in

place based on the initial investigation and the concerning trend in outcomes continues it may be necessary to reassess and investigate alternative causes considered higher in the pyramid.

The template below may be used by hospital teams as a template for investigation. This can be modified as needed to suit local context.

References

1. NELA Project Team. *Fourth Patient Report of the National The third Patient Report of the National Emergency Laparotomy Audit (NELA)*. (2018). doi:10.1557/opl.2014.223
2. Duckett, S. J., Coory, M. & Sketcher-Baker, K. Identifying variations in quality of care in Queensland hospitals. *Med. J. Aust.* **187,** 571–575 (2007).
3. Eugene, N. *et al.* Development and internal validation of a novel risk adjustment model for adult patients undergoing emergency laparotomy surgery: the National Emergency Laparotomy Audit risk model. *Br. J. Anaesth.* **121,** 739–748 (2018).
4. A Local Story - NELA team progression in Leeds - The National Institute of Academic Anaesthesia. Available at: https://www.nela.org.uk/NELA-team-progression-in-Leeds. (Accessed: 25th January 2019)
5. Nurse-led pathway improves quality of care for emergency laparotomy patients. *Health Services Journal* (2018). Available at: https://solutions.hsj.co.uk/story.aspx?storyCode=7019620&preview=1&hash=05FA3F2EFEF2979AA924DF09F3DACC2A. (Accessed: 25th January 2019)
6. Mohammed, M. a *et al.* An investigation into general practitioners associated with high patient mortality flagged up through the Shipman inquiry: retrospective analysis of routine data. *Br. Mediical J.* **328,** 1474–1477 (2004).

Template for investigating a change in hospital outcomes (positive or negative)

<table>
<tr><td colspan="2"><u>Data</u></td></tr>
<tr><td colspan="2">- Are the data inputted correctly?
- Are patient risk factors used to calculate expected risk in the model coded appropriately?
- Has there been a change in data collection practices? (e.g. a change in people collecting data, less experienced people collecting the data)
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<tr><td>Possible cause</td><td>Change needed to address cause</td></tr>
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<tr><td colspan="2">- Has there been a change in the care pathway being followed?
- Have new treatment guidelines been introduced?</td></tr>
</table>

Possible cause	Change needed to address cause (if applicable)
<u>Process of care</u>	
- Has there been a change in the care pathway being followed? - Have new treatment guidelines been introduced?	
Possible cause	Change needed to address cause (if applicable)
<u>Professional</u>	
- Has there been a change in staffing for treatment of patients? Have additional staff being recruited to fulfil specialist roles? - Has a key staff member gained additional training and introduced a new method that has led to improved outcomes?	
Possible cause	Change needed to address cause (if applicable)